EXHIBIT B45

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

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IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

MDL NO: 16-2738 (FLW)(LHG)

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THIS DOCUMENT RELATES TO ALL CASES

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DEPOSITION UNDER ORAL EXAMINATION OF SARAH E. KANE, M.D.

January 25, 2019, 9:19 a.m.

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REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR

- - -

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Deposition of SARAH E. KANE, M.D., held at the offices of Sugarman, Rogers, Barshak & Cohen, PC 363 Plantation Street, Boston, Massachusetts, pursuant to Agreement before Janet Sambataro, a Registered Merit Reporter, Certified Realtime Reporter, Certified LiveNote Reporter, and a Notary Public within and for the Commonwealth of Massachusetts, on January 25, 2019, commencing at 9:19 a.m.

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PROCEEDINGS

THE VIDEOGRAPHER: We are now on the record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services. Today's date is January 25, 2019; the time, 9:19 a.m.

This video deposition is being held in Boston, Massachusetts, In Re: Johnson & Johnson Talcum Powder Products Liability Litigation in the United States District Court for the District of New Jersey.

The deponent today is Sarah Kane. Counsel will be noted on the stenographic record. The court reporter is Janet Sambataro and will now swear in the witness.

(Witness sworn.)

MS. AHERN: Just a quick housekeeping matter. The defendants would like to lodge an objection to the additional materials to Sarah Kane that were served yesterday at 3:36 p.m. by Ashcraft law firm. Serving supplementary materials 24 hours before an expert deposition is prejudicial to the defendants' ability to prepare.

The number of the documents that were

identified yesterday in that list are voluminous and dense and require additional time to cover, to the extent that they substantively informed Dr. Kane's opinions in this case.

We'd also like to object to the inclusion of those materials on the science day presentations, which were not intended for any other purpose than for science day in the MDL.

And that's all I have to say on the objections.

MR. ROTMAN: Go ahead.

MR. TISI: First of all, as you know, many of those documents were documents that were provided to counsel in connection with virtually every depositions that have been taken to date. In fact, it was provided with Dr. Mohrman that was being taken at the same time today; it was provided with Dr. Zelikoff earlier in the week; it was provided almost routinely.

Many of them -- some of them, particularly the Health Canada document, were documents that only became available in mid December, number one.

Number two, I believe that the science day document that you're referring to, which I

think you'll find was not relied on in any way, was a -- that was the California and not the MDL. So I just want to be clear about that.

So there is no prejudice, and we would clearly object to -- these are not documents she relied on for her report; they just are supplemental materials. But -- you can ask questions, but we will certainly object to reconvening the deposition at any later time. We made that clear yesterday.

MS. AHERN: Thank you.

MR. ROTMAN: Yeah, there was -- one of the documents was a textbook that Dr. Kane first looked at two days ago or -- yeah, I think it was two days ago, and so I added it to the list. And she brought the textbook with her today.

MR. KLATT: Can I just add we had an agreement for all the other depositions, and I assume we continue today, one objection by a party is good for all.

MR. TISI: That's fine, yes.

MR. ROTMAN: And, you know, just so it's clear to anybody reading the transcript that what you received yesterday was the third reference list that we've provided for Dr. Kane,

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the first being with her report in November; the second being on January 4th, which was about ten days before the deposition had been scheduled for January 14th; and then these additional items were materials that either were inadvertently left off or not reviewed until just very recently.

MS. AHERN: Okay. To the extent that these new materials inform her substantive opinions and were not included in her report or prior versions of the reference list, then we can talk about that later --

MR. TISI: Yeah.

MS. AHERN: -- in terms of additional time.

And just to clarify, Steve, you said that she reviewed one textbook. It looks like on the list that I received, she reviewed the second, fourth, and fifth editions of the textbook --

MR. ROTMAN: I was referring --

MS. AHERN: -- or textbooks.

MR. ROTMAN: I was referring to that as one textbook, yeah, but you're right, the different editions. And she did bring with her

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today those materials.

MS. AHERN: So she has a copy with her today of all of the items listed in the additional materials to Sarah Kane that was served yesterday.

MR. ROTMAN: No.

MS. AHERN: Okay. Do you know what she -- well, we can -- we'll find out.

MR. ROTMAN: Yeah.

MS. AHERN: Okay. All right.

SARAH E. KANE, M.D.,

having been duly sworn, after presenting identification in the form of a driver's license, deposes and says as follows:

DIRECT EXAMINATION

BY MS. AHERN:

Q. Good morning, Dr. Kane.

A. Good morning.

Q. Can you please state your name for the record?

A. Sure. Sarah Kane.

Q. And, Dr. Kane, who is your current employer?

A. Commonwealth Pathology Partners.

Q. And do you have a business address at

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Commonwealth Pathology Partners?

A. The address we commonly use is 81 Highland Avenue, Salem, Massachusetts. It's 01970.

Q. Okay. And do you have any separate consulting business?

A. No. Other -- outside of this type of medical expert witness work, no.

Q. Okay. And how often do you do this sort of medical witness work?

A. I am very new at it. I have done one deposition before in a tobacco case.

Q. Okay. And the fees that you get from these cases, do they go directly to you or do they go to your -- Commonwealth Pathology Partners?

A. They go directly to me.

Q. And, Dr. Kane, you're a medical doctor; correct?

A. Yes.

Q. And what is your medical specialty?

A. I am board certified in anatomic and clinical pathology and cytopathology, with fellowship training in gynecologic pathology.

Q. Does that mean that you review

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diagnostic materials, slides, and blocks that have been taken from patient procedures and make determinations regarding diagnosis?

A. Yes.

Q. Do you see patients as part of your medical practice?

A. Yes. Occasionally, cytopathologists sometimes perform a procedure that's called a fine-needle aspiration. And so if a patient is seen in clinic and the clinician discovers a palpable nodule, I might be asked to go into the room and perform a fine-needle aspiration.

Q. But you don't see patients in the sense that you don't counsel patients and provide ongoing care for an individual patient?

A. Well, I mean, I guess my pathology report is part of the -- basically speaks to medical treatment and informs clinical treatment of the patient. So my pathology reports are seen by the patient.

Q. I guess what I'm getting at is: Do you see patients as part of your practice, give them a history and physical, provide ongoing care for them outside of the setting of a fine-needle aspiration or a specific procedure related to a

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diagnosis?
MR. ROTMAN: Is this working for you?
THE WITNESS: Oh, I'm sorry?
MR. ROTMAN: Is it working?
THE WITNESS: Yes.
MR. ROTMAN: Okay.
A. Outside of the fine-needle aspiration setting, the only time I might see a patient would be with a blood transfusion reaction. I might have to go to the floor to examine the patient or patient chart.
Ongoing care for them outside of the setting of a fine-needle aspiration, the nature of gynecologic pathology, sometimes I will see a Pap smear from a patient and then a cervical biopsy from a patient and then a LEEP from the patient, and I might speak to the clinician about treatment algorithms, that kind of thing.
Q. Do you actually then go see the patient themselves and discuss with them the results of their Pap smear or other testing?
A. Typically, no.
Q. Have you ever performed a history and physical in your practice as a pathologist?
A. Yes.

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Q. Under what circumstances?
A. Under blood transfusion reactions.
Q. And what sort of history and physical do you take in relation to a blood transfusion reaction?
A. Well, you might be looking at blood pressure and review of the medical chart, temperature, that kind of thing.
Q. So you review the medical chart.
Is that medical chart prepared by another physician?
A. Usually, you're looking at retrospective data at the time of the blood transfusion reaction.
Q. How often will you see the same patient who has had a blood transfusion reaction?
A. Not very often.
Q. Okay. Do you ever counsel patients on risk factors for ovarian cancer?
A. Have I ever? Probably, but in my day-to-day practice, I'm not seeing patients on a regular basis to do that.
Q. And the only time you see patients is with regard to specific issues that are within your realm of pathology expertise, a fine-needle

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aspiration, a blood transfusion reaction.
Are there any others?
A. I'm trying to think what another possibility might be.
I mean, I go into the operative room when patients are in surgery sometimes with the surgeon to do intraoperative frozen sections, which are realtime diagnosis while the patient is having a procedure.
Q. But you're interacting with the physicians in that respect, aren't you, not with the patient?
A. It can be both.
MR. ROTMAN: Objection. Objection. You can answer.
MS. AHERN: You can answer.
A. The vast majority of the time I'm with frozen sections, I'm interacting with the surgeon.
Q. Are there times where you are interacting with the patient during a surgical procedure?
MR. ROTMAN: When you say "interacting," you mean having a conversation or do you mean having any kind of contact?

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MR. KLATT: Steve, just limit the objection to "form."
MR. ROTMAN: I'm trying to clarify.
MR. KLATT: It doesn't matter.
BY MS. AHERN:
Q. Did you understand --
MR. KLATT: Object to form.
Q. -- the question, Doctor?
A. Let me -- can -- I'm sorry. Can you read it back or --
Q. You said, "The vast majority of" --
MR. ROTMAN: She's reading, I think.
MS. AHERN: I'll withdraw the question and just remind you.
BY MS. AHERN:
Q. You said that the vast majority of the time you're interacting with the physicians; correct?
A. Yes.
Q. What do you mean by "interacting"?
A. During the surgery, the surgeon might have me come up to the operative room or the surgeon might come down to look at the tissue, both grossly and under the microscope with me.
Q. Okay. Under those circumstances, would

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you ever speak to the patient?
A. Usually not.
Q. And if you -- have you ever spoken to a patient when you were reviewing frozen sections?
A. I might have during rapid reads of fine-needle aspirations. So sometimes interventional radiologists will do fine-needle aspirations if they have to be ultrasound guided. So, yes, I'm speaking to patients sometimes in that situation and, obviously, when I do fine-needle aspirations.
Q. Okay. But you don't have a group of patients that come to you for ongoing care and see you in an office setting, do you?
A. They are basically -- I would say it's the equivalent of physician referral. So if a -- if a clinician is doing a biopsy -- I mentioned women with Pap smears and then cervical biopsies and then cone LEEPs, you know, it's a trajectory of care, but it's physician referred for tissue.
Q. When you say "physician referred," what do you -- what do you mean by that? Are you interacting with the physician in providing advice or recommendations or are you interacting with the patients themselves and providing advice

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or recommendations?
A. The physicians usually.
Q. Okay. So I'm asking about patients.
A. Yeah.
Q. On a given day -- like what are -- what are the days that you're in the office?
A. Monday through Friday.
Q. So are there days that you do particular tasks, administrative, and then days that you do frozen sections or days that you do just general pathology reads?
A. Rarely, I have an administrative day. It would be nice to have more, but, typically, I am looking at slides the majority of the day.
I will be doing frozen sections on some days, but we have a very collegial atmosphere, so I might do frozens with another pathologist. Some days I'm on cytology, so I'm doing the fine-needle aspirations, which is either me performing the fine-needle aspirations or me reading a rapid interpretation that an interventional radiologist has performed.
Q. So on -- in a given week, it's not like you have a patient clinic where patients come to see you and they're scheduled to see you.

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A. That's correct. They're not scheduled to see me.
Q. Okay. And so outside of, like you mentioned, procedures like a fine-needle aspiration, you wouldn't generally see patients directly.
A. The fine-needle aspiration would be the only setting where they would have a scheduled, allotted slot time with me.
Q. Okay. Generally speaking, when you're reviewing slides, what sort of medical records do you have available to you that are relevant to your clinical diagnosis?
A. I have the entire medical record available to me, whatever is in the hospital system for that patient.
Q. What do you routinely rely on or review as part of your review of slides in terms of medical records?
A. Well, it's very patient dependent and very diagnosis dependent, but, for example -- I'll stick to the example of cervical biopsy. So I'll be looking -- if I have a cervical biopsy, I'll look to see the patient's history of Pap smears, HPV tests, that kind of thing.

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Q. Documents that are directly relevant to your review of the current pathology; is that correct?
A. For the most part, I would say so.
Q. In other words, you don't go back through all of their physician records or gynecologic visits, their primary care physician records?
A. Again, it would depend on the situation. I mean, if I have a lung tumor case, I'll probably be looking at the radiology, the radiology reports, the -- I'll pull up a report with a primary care physician to look for smoking history, that kind of thing, to put the whole piece together for the diagnosis.
Q. Okay. And, Doctor, you're here today to provide a deposition as an expert witness on behalf of the plaintiffs; is that correct?
A. Yes.
Q. And you said you've given one deposition in the past?
A. Yes, that's correct.
Q. And what sort of case was that?
A. That was a tobacco case.
Q. Were you an expert in that case?

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A. Yes. It was an individual causation case.
Q. Okay. Were you an expert for the plaintiffs or the defendants?
A. For the plaintiffs.
Q. And what sort of -- what sort of case was that in terms of the injury that was being alleged?
A. It was a patient with lung cancer who was suing a tobacco company.
Q. And what was your specific -- what was your opinion in that case?
A. That it was highly likely that her long history of smoking caused her lung cancer.
Q. So -- and I should have gone over this with you in the beginning, but you're familiar with the deposition rules?
A. In general, I think.
Q. Okay. You're doing a very good job. And the main things to remember is the two of us will try not to speak over each other so that the court reporter can take a clean transcript down.
If you need a break at some time, that's fine, just let me know. All I ask is if there's a question pending, you go ahead and finish the

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answer to the question and then we'll take a break.
If you don't understand a question that I ask you, please don't answer it. Let me know that you don't understand the question or you'd like me to rephrase it and I'll be happy to do that. All right?
A. Okay.
Q. Okay. And if you answer the question, is it fair for me to assume that you understood it?
A. Yes.
Q. All right.
(Notice of Oral and Videotaped Deposition of Sarah E. Kane and Duces Tecum marked Exhibit 1.)
BY MS. AHERN:
Q. Doctor, I'm handing you what's been marked as Exhibit No. 1 to your deposition.
MS. AHERN: I don't know how many people need copies of these. I don't have that many, but --
MR. TISI: I'll take a copy. Thank you.
MR. ROTMAN: Thank you.

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MS. AHERN: You're welcome.
BY MS. AHERN:
Q. Dr. Kane, I've handed you a copy of your Notice of Deposition for today.
Have you seen this document before?
A. Yes.
Q. When did you see it?
A. I believe it was sometime in December, because the original deposition date was January 14th.
Q. And, Doctor, do you know whether you produced all of the documents that are responsive to the request in Exhibit 1, your deposition notice?
MR. ROTMAN: We've objected to a number of them. And so she's producing -- you should go item by item, I think, if you want to -- I'm going to object otherwise.
Q. Doctor, do you know what you brought with you today?
A. Yes. We have my -- a copy of my updated CV. We have copies of my invoice. I believe I have a copy of -- oh, right. Sorry.
I have pages that I found for the Blaustein second edition, which I don't have the actual

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textbook. I believe I got -- I found this image off of the internet. But I do have the fourth and fifth editions of the Kurman Blaustein's textbook, and I've marked any relevant pages that I reviewed a couple of days ago.
MS. AHERN: If you --
MR. ROTMAN: One second.
MS. AHERN: It might be easier if you just hand me those and let me take a look.
MR. ROTMAN: In addition, there's the boxes in the room that are the documents that were sent up by counsel from Ashcraft & Gerel.
MS. AHERN: Thank you.
BY MS. AHERN:
Q. All right, Doctor. So let's take these in order, I guess. Let's look at your --
MR. ROTMAN: She also has a copy of her report.
MS. AHERN: Okay. We'll mark your updated CV as Exhibit No. 2.
(Curriculum vitae of Sarah E. Kane, M.D. marked Exhibit 2.)
BY MS. AHERN:
Q. Do you need a copy in front of you?
A. Sure.

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Q. Okay.
MS. AHERN: I don't know if anyone else needs a copy.
BY MS. AHERN:
Q. Doctor, Exhibit 2, this is a copy of your current curriculum vitae?
A. Yes. January 2019, yes, this is the current.
Q. And can you tell me what has been updated since you submitted your report November 15th of 2018?
A. I believe the only change is that I am now director of cytopathology at North Shore Medical Center, which includes Salem Hospital and Union Hospital, which is in Lynn, Massachusetts.
Q. Are there any additional publications that you have included on your updated resume -- or, sorry, updated CV?
A. I don't believe so.
Q. The only change is that your position has changed to director?
A. Yes, of cytopathology.
Q. Okay. And you've also brought with you invoices --
A. Yes.

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Q. -- for your time spent on talc?
A. I handed them to her. Yes.
MR. ROTMAN: What we handed, I think, is multiple copies, so you can hand one back, I suppose.
MS. AHERN: We'll mark as Exhibit 3 to your deposition an invoice for rendered services.
(Invoice from Sarah Kane, M.D., for services 5/19 through 7/14 marked Exhibit 3.)
MS. AHERN: I can't see a date, but it looks like it covers -- well, let's just have you look at it.
BY MS. AHERN:
Q. Can you tell me the date range covered by that invoice?
MR. ROTMAN: Copy for me?
A. Yes. It looks like it is from May 19th to June 16th. That would be -- if this is the first invoice, I believe, that would be of 2017, year 2017.
Q. Okay. And, Doctor, was this May 19, 2017 -- how long after you were retained did you submit this invoice?
A. I wouldn't have sent it until after

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June 16th, which is the last date. So it would have been after June 16th, 2017.
Q. I'm sorry. Do you remember when you were retained by the plaintiffs to be an expert in this litigation?
A. I believe I was contacted by Mr. Rotman in early May of 2017.
Q. Okay. Do you know how Mr. Rotman found your name?
A. I believe he was referred by a colleague.
Q. Do you remember what colleague that is?
A. Dr. Paul Michaels.
Q. And is Dr. Michaels a pathologist?
A. Yes.
Q. Where does Dr. Michaels work?
A. I actually don't know the name of his group, but he is in Austin, Texas now.
Q. Where was he in 2017?
A. Austin, Texas, I believe.
Q. Okay. Is he a gynecologic pathologist?
A. No.
Q. What type of pathologist is he?
A. He has a cytopathology fellowship, in addition to anatomic and clinical board

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certification.
Q. And how do you know Dr. Michaels?
A. We were residents and fellows together.
Q. Were you -- fellows where? Mass General?
A. At Massachusetts General, yes.
Q. Was he in the gynecologic pathology fellowship with you or a different fellowship?
A. So my fellowship was kind of interesting. I was, unfortunately, one of the last groups where a combined anatomic and clinical pathology residency was five years. I think the next year after I began residency they dropped it to four years.
So my surgical pathology and cytopathology, it was a two-year fellowship. The gyn path and the cytopathology, it was over a two-year period. And the weeks of gynecologic pathology were mixed with weeks of cytopathology, so they spread out the cytopathology fellowship over two years.
Paul was a cytopathology fellow the first year of my fellowship, so we did all four years of anatomic and clinical pathology and then the first year of fellowship at the same time.
Q. Okay. And looking back at Exhibit 3,

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this invoice from May 19, 2017, to July 14 of 2017, the first entry looks like it's -- it covers a period of May 19th through July 14th, "Communication with firm regarding talc litigation case, one hour"; is that correct?

A. Yes. Sorry. Thank you for correcting me. I saw the last line, 6/16, and figured that was the last day that this covered. But you're correct, it's -- July 14th would have been the last date that this invoice covered.

Yes, June 16th I met with Mr. Rotman, Dr. Thompson, and Mr. Soileau -- I don't know how to pronounce his last name.

Q. Are they all -- they're all attorneys; correct?

A. Correct.

Q. Okay. What firm?

A. I know Mr. Rotman is with Hausfeld. Dr. Thompson is with Allen Beasley. I don't know for sure where Mr. Soileau is from.

Q. You said Mr. Thompson is with Beasley Allen.

A. I believe so. I don't remember for certain.

Q. And at least during --

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MR. ROTMAN: It's Ms. Thompson.

MS. AHERN: Ms. Thompson.

MR. ROTMAN: Or Dr. Thompson.

THE WITNESS: Doctor. She's a -- she's a doctor, as well as an attorney.

Q. And for this first invoice, you billed $26,666.67; correct?

A. Yes.

Q. And you spent a total of 53 hours and 20 minutes working on talc-related issues?

A. Yes.

Q. Seventeen hours and five minutes of that was reviewing the medical literature, expert reports, and testimony; is that correct?

A. So this was my first time ever recording any sort of invoice for medical expert witness work, so the review of medical literature, expert reports, and testimony, probably some of that will also be included in the generating of medical expert report, because while I was -- I basically began -- you can see from the dates I pretty much started drafting, taking notes in a draft, around May 28th, which was soon after I did my initial medical literature searches.

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So those hours overlap a little bit. I mean, I kept track of particular hours so that I could bill accurately, but those two things -- certainly, generating the medical expert report would also include review of medical literature.

Q. Okay. So you started on your -- on the draft of your expert report in this case back in May of 2017; is that correct?

A. Late May, yes.

Q. And did you -- do you remember when you started your review of the medical literature? Would it have been May 20th, as reflected in this invoice, Exhibit 3?

A. Yes, I believe so.

Q. You also have on here that you spent some time researching electron microscopy experts.

A. Yes.

Q. Was that at the request of the plaintiffs' counsel?

A. Plaintiffs' counsel was looking for additional people because there are very few electron microscopy units in the country and very few expert electron microscopists.

I can't remember if they asked me to or I

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offered to. It could have been the latter. But I was aware that they were looking for additional people to potentially use electron microscopy.

Q. Do you know how plaintiffs intended to use the electron microscopy experts?

MR. ROTMAN: Objection. That's going into areas that you're not entitled to, so she's not going to answer that.

BY MS. AHERN:

Q. Doctor, what sort of electron microscopists were you looking for at the plaintiffs' request?

MR. ROTMAN: Same objection.

MS. AHERN: I'm not asking her about communications that she had with counsel; I'm asking her what sort of work --

MR. ROTMAN: Your question --

MS. AHERN: -- she did --

MR. ROTMAN: Your question --

MS. AHERN: -- that she was paid for by the plaintiffs' counsel and that's reflected on the invoice that you've submitted here today.

MR. ROTMAN: You are asking her what she was doing at plaintiffs' counsel's request. That's unrelated to her --

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MS. AHERN: You're --
MR. ROTMAN: -- opinions.
MS. AHERN: -- instructing her not to answer the question of, "Doctor, what sort of electron microscopists were you looking for at plaintiffs' request?"
MR. ROTMAN: Yes. I'm objecting to that.
MR. KLATT: That's not a communication.
MS. AHERN: That's not a communication. That is what did she do and what was she looking for.
MR. TISI: It's consulting.
MS. AHERN: She's sitting here today as a testifying expert.
MR. ROTMAN: Understood. She's not going to answer that.
BY MS. AHERN:
Q. Doctor, did you make any recommendations regarding electron microscopists?
A. No, ultimately, I did not give them any names.
Q. What electron microscopists were you looking at when you were conducting your research?

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MR. ROTMAN: Again, this is her work on -- as a consultant not relating to her opinions in this case --
Q. Doctor, do you --
MR. ROTMAN: -- so you're not entitled to this information.
MS. AHERN: You're instructing her not to answer.
MR. ROTMAN: Yes.
MS. AHERN: Then instruct her not to answer.
MR. ROTMAN: I'm instructing you not to answer.
THE WITNESS: Okay.
BY MS. AHERN:
Q. Doctor, do you know any electron microscopists?
A. Yes.
Q. Who?
A. I know Dr. Gunnlaugur Nielsen at Massachusetts General Hospital.
Q. How do you spell Gunnlaugur's name?
A. G-U-N-N -- I believe there are two Ns -- L-A-U-G-H-E-R [sic], Nielsen. That's with an S-E-N. But he goes by Petur, which is

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P-E-T-U-R.
Q. N-I-E-, Nielsen?
A. I believe so.
Q. -S-S-O-N?
A. No, -L-S-E-N.
Q. Did you speak to Dr. Nielsen about potentially working on the talc litigation?
A. I believe I e-mailed him.
Q. Do you remember when that occurred?
A. It was probably -- I don't remember exactly, but I would imagine it was between 5/22 and 6/1 of 2017.
Q. And was he interested in doing any talc work?
A. He was not interested in doing medical expert witness or consulting work.
Q. Did you e-mail anybody else, any other electron microscopists?
MR. ROTMAN: So you keep on asking her about the consulting work that she was doing that had nothing to do with her opinions in this case, which is why we're here today. We're not here today for you to take the deposition of her consulting work at that stage on this issue, so that whole area is off limits and I'm instructing

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her not to answer. If you want to continue asking those questions, I'm going to continue to object on the same basis.
Q. Doctor, did you contact any electron microscopists who agreed to work on the talc litigation?
MR. ROTMAN: Objection.
Instruct you not to answer for the reasons previously provided.
Q. Doctor, do you know a Dr. Campion?
A. I do not.
Q. Do you know a Dr. John Godleski?
A. I know the name. I do not know him personally.
Q. Do you know Bill Welch?
A. I know the name. I do not know him personally.
Q. Okay.
(Invoice from Sarah Kane, M.D., for services 7/28 through 9/12 marked Exhibit 4.)
BY MS. AHERN:
Q. Doctor, I'm handing you what's been marked as Exhibit 4 to your deposition. Can you tell me what that is?

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A. This is probably the second invoice. Again, I don't believe I had it numbered on the actual invoice, but this looks like it would be the second invoice.
Q. And what period of time does Exhibit 4 cover?
A. This covers July 28th to September 12.
Q. Is this 2017?
A. Yes.
Q. And you spent an additional 37 hours and 40 minutes reviewing literature and generating your expert report; is that correct?
A. Right. And you'll see I actually combined everything, because it got too complicated to separate them out. And generating the medical expert report was sort of this organic part of reviewing the literature.
Q. And the total bill was for $19,666.67; correct?
A. Yes.
Q. Okay. Was all your time on Exhibit 4 spent working on your MDL report?
A. I'm sorry. This invoice?
Q. Yes, ma'am. Was the time spent on Exhibits 3 and 4, these first two invoices, was

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this all in relation to your work on the talc MDL?
A. Yes. I'm not involved in any other talc litigation.
Q. Okay.
MS. AHERN: Okay. I'm marking Exhibit 5 as -- oh, I'm marking, sorry, your third invoice as Exhibit 5 to your deposition.
(Invoice from Sarah Kane, M.D., for services 9/18/17 through 2/5/18 marked Exhibit 5.)
BY MS. AHERN:
Q. This is a copy of an invoice submitted by you; correct?
A. Yes.
Q. And what dates does it cover?
A. This covers September 18th, 2017, to February 5th, 2018.
Q. You spent an additional 27 hours and 40 minutes working on your report; is that correct?
A. Yes. Well, 21 hours, 55 minutes reviewing the literature and the medical expert witness report, and then there were a few hours communicating and meeting with the firm, which would likely be Mr. Rotman.

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Q. Who's been your primary contact?
A. Mr. Rotman.
Q. Okay. And a total for that bill was $13,835; is that correct?
A. Yes.
(Invoice from Sarah Kane, M.D., for services 2/23/18 through 8/3/18 marked Exhibit 6.)
BY MS. AHERN:
Q. I'm handing you what's been marked as Exhibit 6 to your deposition.
Can you tell me what that document is, please?
A. So this -- I'm counting now -- looks like this is the fourth invoice -- yes, the fourth invoice that I sent them.
Q. And what period of time does this Exhibit 6 cover?
A. It looks like February 23rd, 2018, through August 7th, 2018.
Q. Okay. And Exhibit 6 reflects that you spent an additional 16 hours and 55 minutes reviewing literature and generating your medical expert report; is that correct?
A. Yes.

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Q. And 3 hours and 30 minutes communicating or meeting with the law firms involved.
A. Correct.
Q. Okay. And the total for that invoice was $10,208; correct?
A. Correct.
Q. Okay. I'm handing you what's been marked as Exhibit 7 to your deposition.
(Invoice from Sarah Kane, M.D., for services 9/20/18 through 11/16/18 marked Exhibit 7.)
BY MS. AHERN:
Q. And this is another invoice prepared by you?
A. Yes.
Q. And the period of time that is covered appears to be September 20th, 2018, through November 16th of 2018; is that right?
A. Yes.
Q. And you spent an additional 71 hours and 5 minutes reviewing materials and generating your expert report?
A. Yes.
Q. And about four-and-a-half hours

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communicating with the law firms involved?
A. That's correct.
Q. For a total of $37,791.67?
A. Yes.
Q. Doctor, do you have any -- this takes us through -- this last invoice, Exhibit 7, takes us through November of 2018.
You've done additional work since November of 2018; correct?
A. I have.
Q. Do you know how much time you have yet to invoice or -- sorry, let me back up. Withdraw that.
Have you sent another invoice to plaintiffs' counsel?
A. I have not.
Q. Okay. Do you have any idea how many hours you have yet to invoice?
A. I have not added it up. I don't really have a ballpark. Maybe -- I would just be guessing. I haven't added it up, to be honest.
Q. Do you know how much money you've made to date, totaling all of these together?
MR. ROTMAN: Objection.
Q. How much money -- how much money have

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you made in fees associated with your talc work to date?
A. I would need a calculator to add it all up, but this would be the full amount, all added together.
Q. And, Doctor, you're charging $500 an hour; correct?
A. Yes.
Q. Did you ask for a retainer when you were initially asked to get involved in the case?
A. I did not.
Q. Were you offered a retainer?
A. It wasn't discussed.
Q. Does the amount that you charge or your fee, does that change with the activity that you're performing?
A. No. I think I had a fee schedule where trial might be on a per-day basis, but I don't remember what that is.
Q. Did you actually submit a written fee schedule to the plaintiffs' counsel?
A. I believe I did at some point.
MR. ROTMAN: I don't know. I don't recall that.
Q. Could you find a copy of that, please,

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and produce it to one of the attorneys involved?
A. Sure.
Q. Thank you.
MR. ROTMAN: She'll find it if it exists. She'll look for it.
MS. AHERN: Clearly.
MR. ROTMAN: She didn't testify that she produced a fee schedule; she said she believed she did.
MS. AHERN: Understood. If she finds it --
MR. ROTMAN: Yeah.
MS. AHERN: -- she'll produce it to you and you'll produce it to us.
MR. ROTMAN: Exactly.
BY MS. AHERN:
Q. Doctor, how much -- I mean, how do you keep track of your time? Do you have a spreadsheet? Do you have some process where you log your hours?
A. I keep a list, an electronic list. It's not an Excel, but it's just a list.
Q. So is it just a Word document and you put your time entries in and multiply that by your hourly rate?

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A. Basically.
Q. And do you generate the invoices yourself?
A. I do.
Q. Is that through some sort of program or is this just a Word document that you created and you plug the information in?
A. It's just a Word document.
(Discussion off the record.)
BY MS. AHERN:
Q. So, Doctor, other than the folders that we've just gone through, is there anything related to your opinions in this case that you did not bring with you to the deposition today?
MR. ROTMAN: Objection.
Q. Start with that.
MR. ROTMAN: Objection.
A. I believe I brought all of the literature cited in the initial reports. I've tried to be complete, as you know, with listing everything that I've reviewed. It's possible there might have been some things that I reviewed that I forgot to put on a list, but I've tried to be as complete as possible.
Q. How did you track your literature

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reviews?
A. So when I was writing the report, you'll notice the first reference list is a list of papers that I actually cited in the text of the report, and then I had -- any papers that I reviewed or other data that I reviewed, I kept in folders on my computer.
Unfortunately, I had two hard drives malfunction while I was in the process of writing this report. Luckily, I backed up most of it, so it's possible a few things didn't get documented, ultimately, but I really tried my best to make it complete and accurate, and that's why you got another list yesterday.
Q. Okay. And, I'm sorry, we forgot to mark some of these.
And so can you tell me -- this is something you brought with you today?
A. Yes.
MR. TISI: Can I -- and he's defending the deposition; I just have a little more knowledge of the documents and how they -- at least I think I do.
I think that in the boxes here are the references cited. The materials considered, I

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don't think we printed out. I don't think those are in the boxes. And so I don't want there to be any -- there are documents she reviewed that are not here that are not referenced, but were identified in that list.
Does that make sense?
MS. AHERN: Maybe. I'm going to go through the various reference lists with her --
MR. TISI: Okay.
MS. AHERN: -- and we can kind of clarify as we go.
MR. TISI: Like, for example, I mean, I just -- I'm just using an example -- we supplemented with some Health Canada materials. I don't know if she brought those with her, because they were not in the original report. They weren't available at the time, so they would not be in the reference materials that are in the binders.
I know you haven't cracked open the boxes, but I don't want there to be any misimpression. So in terms of what they are, you can certainly ask her, but she may not know what is in the boxes, because we printed them out for her. Do you know what I'm saying?

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MR. KLATT: Chris, let me just clarify. There's four blue cardboard TLS boxes --
MR. TISI: Correct.
MR. KLATT: -- that you're referring to?
MR. TISI: Correct.
MR. KLATT: And they have binders in them?
MR. TISI: They have binders in them. And I haven't even looked at them because they were sent out from the Ashcraft office, but my understanding -- and you can crack them open at break -- but my understanding is there are copies of those. I don't know how many. So it's four boxes, but there are duplicates in there.
But they are -- if I understand -- and I can correct them on a break -- if I understand them, they are copies of the references. We did not make copies -- or they did not make copies of the materials that were considered but not referenced in the reports.
Do you follow what I'm saying?
MR. KLATT: Yeah. What I want to clarify is the four boxes here have not been in Dr. Kane's possession, so there's no notations,

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highlighting, stickies --
MR. TISI: Oh, no.
MR. KLATT: -- that she -- that Dr. Kane herself would have put on what's in the boxes --
MR. TISI: No. Those were print- --
MR. KLATT: -- is that correct?
MR. TISI: Correct. Those were printed out by the plaintiffs' steering committee. Basically, we took her reference list and printed them out for you all. There's no -- there are no notes from her or anything like that.
What I don't think we printed out for you would be the extensive documents that she reviewed, including the supplemental materials that were identified, and then put them -- we can provide those in a -- you know, on a thumb drive if you want to. It's just in these depositions we've had so far, half the time the boxes aren't even opened, and we didn't want to just create paper for the purpose of creating paper. But if you want, we can pull those for you and put them in a Dropbox or whatever.
I don't want to waste your time, because I do want there to be -- because she

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doesn't necessarily know what was printed out for her.

MS. AHERN: Understood. So let's --

MR. TISI: I'm sorry if I --

MS. AHERN: That's okay.

MR. TISI: -- took up time.

(Excerpt from Blaustein's Second marked Exhibit 8.)

BY MS. AHERN:

Q. Doctor, I'm handing you what's been marked as Exhibit 8 to your deposition.

A. Yes.

Q. Is this something that you brought with you today in response to the Notice of Deposition?

A. It's something I brought because I reviewed it a couple days ago. It probably falls within the deposition. I know you wanted to see everything that I reviewed.

Q. So, first of all, tell me what this is. What is Exhibit 8?

A. This is a page from Blaustein's second edition of the Pathology of the Female Genital Tract.

Q. Do you know what page it is?

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A. Unfortunately, it is cut off. This -- I don't have this textbook. I found this, I think, on Google Books, actually.

Q. And so why are you bringing it today again?

A. Because I reviewed it.

Q. Okay. And why did you review this?

A. Well, I recently became aware that Dr. Kurman is a medical expert witness for the defense, so I was more curious. I actually asked the plaintiffs' attorneys for a report -- any report that Dr. Kurman had done, because I was trying to understand his -- what his viewpoint might be. I don't have his defense report because they're not available to us yet, but I was trying to get a sense for what defense medical experts -- their viewpoints.

And so I did a search for, basically, "talc" and "Kurman" and I found this (indicating). And then I have two other editions, so I looked through my other editions for any references to talc. Because Kurman edited the fourth and fifth edition. I do not believe he edited the second edition, which is -- this one page is from (indicating).

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Q. And, Doctor, the additional materials to -- of Dr. Sarah Kane that were provided to us yesterday, you list "Kurman defense report" from a case by the name of Ristesund.

Did you not receive that?

A. I asked for -- yeah, I did receive that.

Q. You received it?

MR. ROTMAN: What she -- what she was saying is she --

MS. AHERN: Wait. I'm asking her the question.

Q. Did you receive the report, the Kurman defense report, from a case by the name of Ristesund?

A. Yes. I had requested a defense report written by Kurman, if they had anything, and that is what I received.

Q. Okay. I thought just a minute ago you said you had not received one because it wasn't available to you.

A. I'm talking about the MDL, the curr- --

Q. Ah.

A. -- the current defense expert witness reports.

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Q. Okay.

A. Yeah.

Q. Thank you for the clarification.

So you have seen at least one defense report that was written by Dr. Bob Kurman; right?

A. Yes.

Q. And did you -- do you know Dr. Robert Kurman, either personally or by reputation?

A. By reputation and I've gone to dinner with him before, but I don't know him well.

Q. And what do you know about Dr. Kurman?

A. So he is a well-known gynecologic pathologist out of -- he was out of Johns Hopkins. I believe he recently retired.

But he certainly edited one of the main gynecologic pathology textbooks and was -- you know, published quite a bit in gynecologic pathology, so his name is well known in our community.

Q. And you've actually cited to a number of his papers in your report; correct?

A. Yes, I'm sure I have. I know at least one or two.

Q. And Dr. Kurman was a Robert Scully fellow, as well, wasn't he?

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A. I actually don't remember if he trained under Scully. It's possible. I don't remember whether or not he did.
Q. Okay. This Exhibit 8 that you brought with you today, are you bringing it here because it mentions granulomatous endometritis caused by foreign bodies?
A. It says, "Talc may be introduced into the endometrial cavity by instruments contaminated with talcum powder or by gloves during a pelvic examination. Patients may be asymptomatic or may present with menorrhagia. Microscopically, the extent of the granulomatous inflammatory reaction depends on the quantity of the talc inoculated. The infiltrate is characterized by histiocytes and foreign-body multinucleated giant cells surrounded -- surrounding the talc crystals, along with lymphocytes and plasma cells. The crystals appear as refractile, birefringent, needle-like, or fan-shaped splinters in polarizing light."
Q. Are you familiar with the type of reactions -- tissue reactions that are elicited by talc in tissue?
A. I know -- I'm aware that you can get

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granulomous -- granulomatous inflammation, like here, and you can have acute inflammation, for example, in pleurodesis and chronic inflammation, like lymphocytes and plasma cells.
Q. Are you an expert in granulomatous inflammation?
A. Well, I certainly am familiar with the -- with diagnosis of granulomatous inflammation. I see it quite commonly.
Q. Under what circumstances do you commonly see granulomatous inflammation?
A. You see it often in -- the most common situation would be foreign-body giant cell. That could be due to foreign bodies or it could be due to -- a common situation we might see them is what's called an epidermal inclusion cyst in the skin, and you actually can get a granulomatous response to keratin that has -- if it's ruptured and gone into the dermis, you can see that.
Infections is another one. In tuberculosis, you can see granulomatous inflammation. Fungal infections, you can see granulomatous inflammation.
Q. How many different types of granulomatous reactions are there?

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A. I'm not really sure what you mean by "types." You mean foreign body versus infectious versus --
Q. Yes.
A. Those would be the top of the list.
Q. And are there subtypes of granulomatous inflammation within those categories?
A. Well, you can have multinucleated giant cells that aren't part of a granuloma.
You can see -- another common situation where you'll see granulomas is in Crohn's disease. That's granulomatous inflammation in the colon due to inflammatory bowel disease.
And I think -- yeah. So foreign body and infection are -- and certain diseases that may cause granulomatous -- that's sort of the hallmark of that type of disease, sarcoidosis.
Q. Have you ever -- the Figure 12.6 in Exhibit 8 actually doesn't have anything to do with granulomatous endometritis, does it?
A. No. That figure is of a type of finding you can see in the endometrium that's not a granulomatous reaction.
Q. And how did Exhibit 8, if it does, inform your opinions in this case?

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A. Well, it was just a piece of information I found, again because I was curious mostly about what Kurman's opinion might be on this litigation. So...
Q. Does -- do you know what -- did this come from a particular chapter in Blaustein's second edition?
A. This, I don't -- I have no more information on this particular one. Um --
Q. Do you know who authored the chapter?
MR. ROTMAN: Excuse me. I think she was in the middle of an answer.
Q. I didn't mean to cut you off. Please go ahead.
A. Again, I don't have any more information. I brought it because I saw it.
Q. Okay. So you don't know who authored the chapter that contains this information in Exhibit 8?
A. Not for this edition, I do not.
Q. And are you -- do you -- did you say earlier you weren't sure if Dr. Kurman edited this particular version of Blaustein's Pathology?
A. I don't believe he did. I know he edited the fourth and fifth, but I don't believe

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he did the second.
Q. Does the information in Exhibit 8 inform your decisions regarding talc and causation with regard to ovarian cancer?
MR. ROTMAN: Objection.
A. It's another piece of evidence. It mentions granulomatous inflammation due to talc in the endometrium.
Q. And what does that have to do with ovarian cancer?
A. Well, one of the plausible biologic mechanisms for talc causing ovarian cancer is that it elicits a chronic inflammatory reaction.
Q. And there are different types of chronic inflammatory reactions, aren't there?
A. Yes, there are.
Q. Is a foreign-body reaction the same as the type of inflammation seen, for instance, in ulcerative colitis? If you know.
A. No, I'm just rereading the question.
Ulcerative colitis, you don't typically see foreign-body reaction.
Q. Ulcerative colitis is one of the conditions that has been associated with the development of cancer; correct?

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A. Those with ulcerative colitis have an increased risk of colon cancer, yes.
Q. Do you know of any particular cancers that have been linked to foreign-body responses?
A. Well, foreign-body responses -- for example, asbestos is known to cause an inflammatory response and asbestos is known to cause mesothelioma and lung cancer, and the IARC states that it causes ovarian cancer.
Q. And how is the response to asbestos different from the response that's been documented with talc in terms of tissue reaction?
A. So you can see a granulomatous reaction to talc. You can see an acute reaction to talc in pleurodesis patients.
This page here mentions plasma cells and lymphocytes, which you do see in Crohn's disease.
Q. You see plasma cells and lymphocytes in a number of different inflammatory conditions; correct?
MR. ROTMAN: You can answer.
A. Yes, you can see lymphocytes and plasma cells in inflammatory conditions.
Q. And you can see inflammatory con- --
MR. ROTMAN: Object -- object -- I was

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going to --
MS. AHERN: One second, please.
Q. You can see inflammatory conditions that are not in any way linked to the development of cancer; correct?
A. So not all chronic inflammation is going to lead to cancer, but chronic inflammation is a well-established cause of different types of cancer.
MR. ROTMAN: I'd like to take a break. We've been going a little over an hour.
MS. AHERN: Okay.
THE VIDEOGRAPHER: Here ends Media 1. Off the record, 10:21 a.m.
(A recess was taken.)
THE VIDEOGRAPHER: Here begins Media No. 2 in today's deposition of Sarah Kane, M.D. Back on the record, 10:37 a.m.
BY MS. AHERN:
Q. All right. Dr. Kane, we were -- we left off, we were talking about chronic inflammation and cancer.
Do you remember that?
A. Yes.
Q. Okay. Can you identify for me the

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types of ovarian cancer that have been associated with chronic inflammation?
A. So we know that endometriosis, as an example, causes an inflammatory response. The types of ovarian cancer that are associated with endometriosis are clear cell carcinoma and endometrioid carcinoma.
Q. Are there other forms of ovarian cancer that are associated in the literature with chronic inflammation?
A. So we do see chronic inflammation within other types of ovarian cancer, so high-grade invasive serous, low-grade serous carcinoma, you do see chronic inflammation within those tumors.
Q. Let me be more precise, because it's sort of a chicken and the egg kind of thing.
I'm asking what sort of inflammatory conditions have been associated with the development or the cause of ovarian cancers?
A. Yeah. So the mechanisms of a lot of ovarian cancer have been somewhat elusive. Unfortunately, it's a rare disease. It's hard to study. It's difficult to have sort of a large enough cohort to really get good data on ovarian

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cancer, and so we don't really know all of the mechanisms of the initiation of ovarian cancer.

But we know that chronic inflammation, we see it in ovarian tumors. We know that -- and putting it in a talc perspective, we know that talc can cause chronic inflammation and so -- and we know that chronic inflammation causes other types of cancer.

Q. So is that -- can you name any other types of ovarian cancers that have been associated in the literature with chronic inflammation in terms of a specific etiology for that cancer?

A. So, again, I would say I don't know if we can say for certain what the specific etiology is for all types of surface epithelial cancer, but we do know that, again, clear cell has been associated with endometriosis, which causes chronic inflammation, and we see chronic inflammation in tumors. But the mechanisms for these types of tumors have not been completely mechan- -- elucidated.

Q. So do you not know of any other specific ovarian tumors that have been associated in the literature causally with chronic

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inflammation?

A. Again, I don't believe that the mechanisms of all of these tumors have been elucidated completely.

Q. And I do understand your answer, but I just want to know if there are -- if you're aware of literature connecting causally chronic inflammation with other types of ovarian cancer other than the two that you've mentioned, endometrioid and clear cell carcinoma.

A. Well, again, I mentioned that in serous tumors, we do see chronic inflammation in those tumors.

And with smoking and mucinous ovarian cancers, you know, it's been -- there's some literature that suggests, you know, smoking is associated with mucinous and those -- that can cause inflammatory reactions.

But, again, this is all -- it's not entirely clear what the etiology of some of these tumors are.

Q. You mentioned that in high-grade serous carcinoma, you see associated inflammation; correct?

A. You can see associated chronic

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inflammation, yes.

Q. And you would agree that many, if not most, cancers are somewhat proinflammatory.

A. I think tumors can be -- can be proinflammatory, yes.

Q. So the tumor itself can invoke an inflammatory response during its development; correct?

A. Some tumors will.

Q. And often the tumors will hijack portions of the immune system to help them to grow and metastasize; correct?

A. I'm not sure exactly what you mean by "hijack," but there are mechanisms to -- or literature to suggest that.

Q. So just looking at a high-grade serous carcinoma and seeing inflammation doesn't tell you anything about whether that inflammation caused the tumor or whether it was caused by the tumor; is that correct?

A. So, again, the mechanisms are not that clear, so we don't know for sure. But is all chronic inflammation seen in a tumor the cause of the tumor? I don't know if we know the answer, but, you know, it's definitely an associated

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pattern that we see with ovarian tumors.

Q. So my question is a little different, if I can go back and find it. And it's missing.

My question is: As a pathologist looking at slides from a particular patient who has ovarian cancer --

A. Mm-hmm.

Q. -- just the observation that there is inflammatory cells associated with that tumor doesn't tell you anything, as a pathologist, in terms of whether that inflammation caused the tumor or if the tumor caused the inflammation.

A. Well, I think it depends on the situation. You know, again, for ovarian tumors, if we have a clear cell carcinoma, we could, you know, deduce, especially if you see associated endometriosis, that that is the likely cause, and, again, depending on the patient and the patient's risk factors.

But, yeah, if you're looking just at one slide without any other information, it would be difficult to say.

Q. Well, you would never just be looking at one slide, would you? You'd be looking at all of the slides that were available for a

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particular patient, which would include diagnostic tissue or tumor tissue, as well as normal, nontumor tissue; correct?
A. Right.
Q. Okay. So you would never be in a situation where you're just looking at a single slide and making a determination, unless it's maybe cytology or a biopsy; correct?
A. I'm sorry. I'm just looking at the --
Q. Sure.
A. I'm not sure what the -- the first question came out kind of funny.
Q. What I was saying is there would never be a situation where you're only looking at a single slide to make a diagnostic determination unless it was from a biopsy sample or a cytology.
A. That's what I was going to kind of rewind and clarify, that sometimes there is only one slide. So --
Q. Is that an accurate statement?
MR. ROTMAN: Let her finish the answer. I think she was saying "so" and then you asked another question.
A. So in a larger specimen type, it's correct you would be looking, usually, at more

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slide if there's more tissue that would fit in one cassette to make one slide.
Q. Let's talk about high-grade serous carcinoma.
High-grade serous carcinoma is the most common form of ovarian cancer; correct?
A. It's most -- yes.
Q. By far the most common form of ovarian cancer; is that also correct?
A. It's the most common form, yes.
Q. So let's talk about high-grade serous carcinoma in the context of chronic inflammation.
Do you know of any published literature that connects chronic inflammation causally with the development of high-grade serous carcinoma?
A. I can -- in my report, I actually do have a section. Let me find it.
MR. ROTMAN: It might be easier to take off the clip, if that helps you flip the pages, because it's two-sided.
Q. Doctor, while you look for that, just to the best of your recollection, do you remember reading any studies that concluded that --
MR. ROTMAN: I object. She's in the middle of answering --

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MS. AHERN: I'm not finished with my question. You can object when I'm done with my question.
MR. ROTMAN: I object to you asking a question --
MR. KLATT: She didn't have --
MR. ROTMAN: -- when she's asking --
MS. AHERN: I can ask a question whenever I want. She doesn't have to answer the question if you instruct her not to, but while she's spending time looking through her report, I'm going to ask her a different question based on her recollection.
MR. ROTMAN: Well, you've asked her a question, she's in the process of answering it, and you're asking -- you're asking her a second question. That's what I'm objecting to.
BY MS. AHERN:
Q. Doctor --
MR. ROTMAN: Let her finish --
Q. -- can you answer the question without looking at your report?
A. Well, I'd like to refer to my report if you're asking questions.
Q. And that's fine. My only question,

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really, was, just based on your recollection as we sit here discussing chronic inflammation and ovarian cancer, if you are aware of studies that causally associate chronic inflammation with high-grade serous carcinoma?
A. So there's definitely literature that has looked at associations between chronic inflammation and the resulting sort of expressions.
And that's what -- I was trying to point you to my report on Page 12, the end of it, where it says, "There also is evidence that talc induces macrophage TNF alpha expression and macrophages that express TNF alpha promote ovarian tumor genesis. TNF alpha is involved in chronic inflammation and induces mutations in vitro and TNF alpha-induced chromosomal mutations occur mostly in cells with P53 aberrations and, of note, high-grade serous carcinomas typically have inactivating mutations in P53."
So, again, we don't know all the mechanisms of all of these tumors, but there's certainly literature that is investigating those types of associations.
MR. KLATT: Object. Nonresponsive.

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MS. AHERN: Same.
Q. But since you brought it up, on Page 12 of your report, can you translate for me that paragraph that you just read and put it in lay terms and explain how that has anything to do with causal associations with ovarian cancer and chronic inflammation caused by talc?
MR. ROTMAN: Objection.
A. Well, I think it's there in the report. If talc is inducing macrophage TNF alpha expression and macrophages that express TNF alpha can promote ovarian tumor genesis that occur mostly in the -- TNF alpha-induced chromosomal mutations occur mostly in cells with P53 aberrations, I think that's relevant in looking at evidence that -- for a plausible mechanism that inflammation caused by talc can cause aberrations in -- can cause P53 aberrations. And we know that high-grade serous carcinomas, many of them have P53 mutations.
Q. And high-grade serous carcinomas with P53 mutations, what causes the P53 mutations?
A. Well, again, the literature is still evolving into all of the mechanisms regarding this. Some of them we know are sort of aberrant

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mutations, and we don't always know why they occur.
We know that women with BRCA1 and BRCA2 mutations have -- can get high-grade -- have a higher risk of high-grade serous carcinoma.
But, again, I don't think we know all of the mechanisms that cause, you know, all of these tumors.
MS. AHERN: Objection. Nonresponsive.
Q. Doctor, do you know, as we sit here today, what causes P53 mutations in high-grade serous carcinoma?
A. I think I answered that. We know, I mean, what's in my report and women with BRCA1 and BRCA2 mutations. But, again, the literature is evolving with this.
Q. Doctor, are you suggesting that BRCA1 and -2 mutations cause P53 mutations in high-grade serous carcinomas?
A. What I'm saying is that we know that BRCA1 and BRCA2 mutation patients have a high risk of ovarian cancer.
And so you're asking me what causes, so, you know, I'm telling you the data that we have.
Q. What is the earliest identifiable

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genomic event in the development of high-grade serous carcinoma?
A. So, again, I don't know if I -- I don't know if we always know what the earliest identifiable genomic event in the development of high-grade serous carcinoma is.
Q. Have you reviewed the literature on high-grade serous carcinoma from a molecular genetics perspective?
A. Yes, I reviewed papers on molecular genetics, yes.
Q. Do those papers indicate that one of the earliest, if not the earliest, genomic event in the development of high-grade serous carcinoma that has been identified are mutations in P53?
A. So, again, you can see P53 mutations, for example, in the fallopian tubes and you can have sort of serous tubal intraepithelial carcinomas in the fallopian tube, which are thought to be early precursors for high-grade carcinoma.
Q. High-grade serous carcinoma?
A. Mm-hmm. Sorry, high-grade serous carcinoma.
Q. And do you agree that the STIC lesions

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or serous tubal epithelial carcinomas in the fallopian tubes are currently known to be the earliest manifestation of high-grade serous carcinoma?
A. Well, it depends on what you mean by "manifestation." I mean, it takes a period of time from initial insult until we can recognize something histologically as a precursor to cancer.
Q. That was -- you're right, that was a bad question.
Do you recognize serous tubal intraepithelial carcinomas as an in situ serous carcinoma?
A. I think evidence is supportive of serous tubal intraepithelial carcinomas being a precursor to some high-grade serous carcinomas.
Q. And when you say "precursor," do you mean a frank cancer or a premalignant lesion? What do you mean by "precursor"?
A. Well, again, not -- we don't know if all STICs are going to become high-grade serous carcinomas. STICs were originally discovered in looking at fallopian tubes of BRCA1 and BRCA2 patients that had -- what's the word I'm looking

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for? -- prophylactic salpingectomies to decrease their risk of ovarian cancer.

And that was -- you know, they had evaluated these precursor lesions, and so the thought is that when you have these atypical cells in the fallopian tube fimbria that are -- that have P53 aberrations, that that -- the belief is that that's a precursor to some of the serous invasive carcinomas that we see.

Q. Do you consider STIC lesions to be carcinomas?

A. They're -- the name is intraepithelial carcinoma, so its analogous term would be sort of an in situ cancer.

Q. It is a cancer; correct?

A. Well, they're calling them intraepithelial carcinomas because they have -- I mean, it's sort of semantics. They have a P53 mutation and they're recognizable histologically.

Q. Do you agree that they're carcinomas or cancer?

A. I certainly agree that they can be precursors to invasive serous carcinomas. It's sort of semantics, precursor -- it -- it's -- it's sort of the same question as ductal

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carcinoma in situ in the breast. There's literature that debate about is ductal carcinoma in situ a true cancer or is it a risk factor for cancer, and what is the meaning of treatment for DCIS in the breast? And I would say that that's sort of analogous to STIC lesions in the fallopian tube.

Q. Okay. Do you agree that most high-grade serous carcinomas arise from the endometrial cells in the fallopian tube?

A. High-grade --

Q. Epithelial cells in the fallopian tube. Excuse me.

A. So, again, we -- this was something that the medical community really struggled with, trying to find the precursor lesions to a lot of these tumors.

And for a lot of years it was thought that maybe serous carcinomas derived from what are called epithelial inclusion cysts, so, basically, the thought was that during ovulation, you're disrupting the surface epithelium of the ovary and when the ovary sort of heals itself, you get this invaginated epithelium within the ovary and that maybe because of inflammatory response to

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that ovulation event, you might end up with precursors.

We don't really have a model in a lot of ovarian cancers where you can follow a precursor all the way through to -- what we think is a precursor all the way through to the final tumor. We just -- we don't really have a lot of data on those in-between steps.

So it was very, very interesting when they discovered these STIC lesions in the fallopian tube fimbria that had P53 mutations. It was pretty compelling that these might be the precursor lesions to serous -- high-grade serous carcinomas.

Now, are all high-grade serous carcinomas caused by STIC lesions or are they all -- is a STIC lesion a precursor to all serous -- high-grade serous carcinomas? I don't think we know that.

Q. Do you know of any data associating high -- excuse me, associating chronic inflammation or injury with the development of STIC lesions?

A. So, again, I think the literature is still evolving with this -- these STIC lesions.

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Q. Sorry. Were you finished? I don't want to interrupt you if you're thinking.

A. No, I'm thinking.

Again, I don't think we really have the data on where these STIC lesions are coming from.

Q. As part of your literature review for your MDL report, did you search specifically for papers that might be linking or associating chronic inflammation with early precursor lesions to serous invasive carcinomas or high-grade serous carcinomas?

A. I was certainly looking for literature with the association of inflammation with ovarian cancer.

Q. With -- did you look specifically at the various subtypes of ovarian cancer?

A. Yes.

Q. Is there a particular subtype of ovarian cancer that you think is associated with talc use?

A. So most of the epidemiology literature show the highest association with high-grade serous invasive carcinoma.

Q. When you say "highest association," are you talking about strength of association?

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A. I'm talking about the -- for example, on the cohort studies, they found an association with high-grade serous carcinoma.

And in a lot of the case-control studies, when they looked at tumor subtype, a lot of those tumors were serous carcinomas. Now, some of them broke them out by relative risk by subtype; some of them didn't. I'd have to look at the papers.

Q. Do you remember which cohort study found an association with high-grade serous carcinoma?

A. I believe the Nurses' Health Study. I'd have to look at it to see the numbers.

Q. Was there more than one cohort study that you recall associated talc use with high-grade serous carcinoma?

A. I'd have to look at them just to be sure, but the one that I remember is the Nurses' Health Study.

Q. Are there any other subtypes, histologic types, of ovarian cancer that you believe are associated with talc use?

A. Well, I think talc use -- I think talc use could be associated with the -- any type of surface epithelial cancer. That seems to bear

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out in the epi data. They've certainly seen an association with different types of surface epithelial cancers in the epi data, the strongest association being with the serous invasive.

Q. Have you seen any data supporting an association with talc use and a low-grade serous carcinoma?

A. I'd have -- again, I'd have to look at the different studies to break it out, but I know there was a study that found an increased risk with serous borderline carcinomas. I'd have to look through the individual data sets.

Q. And serous borderline -- are -- serous borderline tumors are not carcinomas; correct?

A. Sorry. I -- serous borderline tumors, yes. I misspoke.

Q. And you don't remember what study that was that associated talc use with serous borderline tumors?

A. I would have to look at the data -- or the study.

Q. So do your opinions in this case apply equally to all histologic subtypes of ovarian cancer or are there specific subtype or subtypes that you are opining are caused by talc?

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A. So I think the most consistent finding is with high-grade serous carcinoma, but there's data for the other types of surface epithelial carcinomas.

Q. And what are the surface types of carcinomas?

A. So they're endometrioid and clear cell, and mucinous less so than, I believe, the endometrioid and clear cell, although I believe, again, in the 2010 Nurses' Health -- is that -- I'd have to go back -- I -- there was a mention of mucinous -- I'm not absolutely sure it was the Gates 2010, but there was a mention of an increased risk of mucinous in one of those studies.

Q. Do you agree that the different histologic subtypes of epithelial ovarian cancer are likely to have different genetic causes?

A. I know they're associated with different genetic mutations.

Q. Do they develop along distinct molecular genetic pathways?

A. That's what the literature suggests at this point.

Q. Do they behave differently?

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A. So the high-grade surface epithelial carcinomas have a more aggressive pathway or presentation. The low-grade surface endothelial carcinomas tend to have a more indolent progression.

Q. You've used the term "surface epithelial carcinomas" and I haven't seen that term generally used in the literature.

When you talk about surface epithelial carcinomas, are you talking about serous or are you talking about endometrioid or are you talking about clear cell? Mucinous?

A. Epithelial carcinomas.

Q. That would encompass all of those, wouldn't it? Wouldn't surface epithelial carcinomas encompass mucinous, clear cell, endometrioid, and serous subtypes? They're all epithelial ovarian cancers; correct?

A. Yes. That's what I'm referring to when I -- because we also have germ cell tumors and stromal tumors of the ovary. Those are much more rare, and I'm not -- you know, I don't think there's associations with those. So, yes, we're talking about epithelial carcinomas, to be clear.

Q. Well, and just -- because I want to

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make sure your testimony is also clear.
So if we could, if you could use the specific subtype names, like serous or endometriod --
A. Okay.
Q. -- or clear cell. That way there's no confusion later on about what you intended.
So when you say -- let's see. Let me go down. Sorry.
When you say "high-grade surface epithelial carcinomas," are you talking about high-grade serous carcinomas?
MR. ROTMAN: Objection. You're asking her to reflect back on all of her prior answers to all of your prior questions, whether she was referring to the same thing in each one?
Q. Do you understand my question?
A. I'd have to figure out what answer you're talking about, but --
Q. So you just -- just a few questions ago, you answered -- I said, "Do the different types -- histologic types develop along the same molecular genetic pathways?"
You said, "That's what the literature suggests at this point."

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I asked, "Do they behave differently?"
And then you responded, "So the high-grade surface epithelial carcinomas have a more aggressive pathway or presentation. The low-grade surface epithelial carcinomas tend to have a more indolent..."
Were you talking about high-grade serous and low-grade serous carcinomas?
A. I was talking -- sorry. I was talking about high-grade serous carcinomas, yeah. And we also have sort of undifferentiated carcinomas that are also considered high grade.
Q. Okay. And were you talking about low-grade serous carcinomas when you said "low-grade surface"?
A. No. So "surface" doesn't really refer to cell type; it's just sort of a --
Q. Right.
A. -- an umbrella term for the epithelial carcinoma.
Q. Right, which is my point. I just wanted to be clear. When you say "surface" --
A. Yes.
Q. -- could you instead use the actual cell type.

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Does that make sense?
A. Okay. Yes. Okay.
Q. Okay. All right. So let me ask my question that I asked a little while again, and you tell me -- you can answer it again with the terminology.
Do the different histologic subtypes of ovarian cancer behave differently?
A. Yes. Again, the high-grade ones generally behave differently than the low-grade ones.
Q. Okay. Do endometrioid and clear cell carcinomas behave differently from high-grade serous carcinomas?
A. The high-grade serous carcinomas tend to behave more aggressively.
Q. Do low-grade serous carcinomas behave differently from endometrioid, clear cell, and high-grade serous carcinomas?
A. They tend to be less aggressive. They all tend to be less aggressive than the high-grade serous carcinomas or other high-grade carcinomas of the ovary.
Q. And are they thought to each have different cells of origin?

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A. Again, we're not entirely sure where these tumors are arising from, particularly with mucinous carcinomas. I think mucinous carcinomas and there's also a type transitional cell, which is very, very rare, and most of the literature, when it comes to the epi data, don't really discuss transitional cell.
But putting that aside, mucinous carcinomas we have, I think, the least amount of data on where they are actually arising from. Clear cell and endometrial carcinomas have an association with endometriosis, but, again, you know, are all cases of endometriod and clear cell carcinomas, are they all arising from endometriosis? I don't think I can say that. I don't think we know for sure.
And serous carcinomas, we talked about the precursor lesions and the fallopian tubes.
So there are differences where we think the tumors are arising from, but, again, I don't think we have absolutes where we can definitively say, you know, this particular tumor in this particular woman arised [sic] from this precursor or...
Q. Okay. And do you know if the different

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histologic subtypes have been associated in the epidemiologic literature with different risk factors?

A. Yes. Again, I think we touched on some of that before. There is an association with endometrioid and clear cell with endometriosis and obesity.

Mucinous carcinomas have shown to be associated in some studies with a smoking history.

High-grade serous carcinomas, it's a little bit harder. We know that BRCA1 and BRCA2 patients have an increased risk.

Q. Now that we're on that topic of genetics, do you know what proportion -- currently, what is believed to be the proportion of ovarian cancers that are caused by germline mutations?

A. Off the top of my head, I think -- do I have that in my report? But I -- I'm thinking it's 10 to 20 percent, but that's off the top of my head.

Q. Have you seen any research coming out of Seattle Cancer Care Alliance over the last 10 or 15 years that indicates the number could be as

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high as a quarter of all ovarian cancers being linked to germline mutations?

A. That would roughly fit with what I just said, 10 to 20 percent. I can't say for sure that I have seen that. I might have. But it fits with what I remember.

Q. I had asked you earlier if you had reviewed any literature relating to inflammatory conditions and associations with early STIC lesions.

And you -- and, I'm sorry, I don't want to misstate your response. What was your response to that?

A. Had I reviewed literature? Yes, I've seen literature.

Q. Okay.

(Article entitled "Serous tubal intraepithelial carcinoma, chronic fallopian tube injury, and serous carcinoma development" marked Exhibit 9.)

BY MS. AHERN:

Q. I'm handing you what's been marked as Exhibit 9 to your deposition. And this is --

MS. AHERN: I don't know if anyone else wants one.

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Q. -- this is an article by Karen Malmberg, et al., entitled "Serous tubal intraepithelial carcinoma, chronic fallopian tube injury, and serous carcinoma development," and it was in Virchows Archives, March of 2016.

MR. TISI: What did you mark this? I'm sorry.

MS. AHERN: I marked this one 9. Thank you. No -- yes, 9.

MR. TISI: Oh, I'm sorry.

MS. AHERN: That's okay.

Q. Do you recall if you've ever reviewed this article?

A. It's possible. It's certainly possible that I have seen this before in just my daily practice. I don't believe I cited it in any of the references that I can remember, but it's highly possible that I've seen it.

Q. Do you see the first page that -- you can just skip if you want, take your time reading it if you'd like, but the authors conclude in their study that there is no correlation with chronic tubal injury or inflammation with the development of STIC lesions or the existence of STIC lesions.

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Do you see that?

A. No. Can you -- I'm sorry, can you point to me --

Q. Oh, sure.

A. -- where?

Q. Do you see the abstract, if you carry it over to the second column?

A. Mm-hmm. Yes.

Q. It says, "STIC and invasive cancer were seen more often in the older patients than in the younger patients"?

A. Mm-hmm.

Q. This study is -- small study, no correlation with chronic tubal injury or inflammation was identified.

A. Yes, with the caveat -- that was a conclusion with the caveat that it was a small study.

Q. Have you -- as a gynecologic pathologist or a pathologist who has subspecialty training in gynecologic malignancies, how often do you see chronic -- or evidence of chronic inflammation surrounding STIC lesions?

Or strike that. How often do you see STIC lesions?

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A. On -- certainly, I can't give you a number. I've certainly made the diagnosis and see it -- I can't give you a number of how many times.
Q. Have you ever been involved in a study looking specifically at STIC lesions and high-grade serous carcinomas?
A. I have not been involved in a study, no.
Q. Have you ever seen evidence of chronic inflammation with a STIC lesion?
A. Off the top of my head, I am not sure. It's possible, but I can't really answer that off the top of my head.
Q. How often do you see chronic inflammation in the fallopian tubes associated with high-grade serous carcinoma?
A. You can certainly see it, but it sort of goes along with the discussion that we had before. You can see chronic inflammation within the tumor, as well.
And so I think, you know, the literature is -- the research is ongoing as to, you know...
Q. So once the tumor -- once there's a lot of tumor burden in the abdominal cavity, it's

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difficult to tell where the inflammation is coming from or what started it; is that correct?
A. Well, if there's chronic inflammation in the tumor, it's likely the tumor has something to do with the chronic inflammation.
But, again, you know, as we talked about before, I think sometimes it is difficult to tell.
MS. AHERN: Okay. Housekeeping matters before I forget.
Let me go ahead somehow and mark -- let's mark -- we can remove this later -- "Blaustein's Pathology of the Female Genital Tract," Fourth Edition, as Exhibit 10 to your deposition.
("Blaustein's Pathology of the Female Genital Tract," Fourth Edition, marked Exhibit 10.)
BY MS. AHERN:
Q. And, Doctor, you brought this textbook with you today.
Is this your textbook?
A. That particular copy is not. That's my coworker's copy. This copy is mine (indicating).
Q. Okay. And inside this, you have what

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looks --
MR. ROTMAN: Just so the record is clear, when you said "this," do you want to identify it?
A. Sorry. The fourth edition belongs to a colleague. The fifth edition is my own.
MS. AHERN: Okay. We'll get to that one. I'll mark that next.
Q. There is a photocopy here, "Blaustein's Pathology of the Female Genital Tract, Fourth Edition," Pages 300 and -- well, Page 376, Page 539, Page 540, 648, 1216, 1217, 1218.
Is this a copy -- are these copies that you made?
A. Yes.
Q. Okay.
MR. TISI: Do you have a stapler? Otherwise I'll get one.
MS. AHERN: No, I don't have one.
MR. TISI: No, I'll go get one.
BY MS. AHERN:
Q. Can you tell me why you made those copies?
A. I made them because it was easier than lugging around a whole textbook. That's why I

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Xeroxed them. But --
Q. You had to bring it anyway.
Sorry. Go ahead.
A. But the particular pages that I copied are ones that talk about granulomatous reactions to talc in the female reproductive system.
Oh, sorry. Okay.
MS. AHERN: Okay. We'll go ahead and mark those copies as Exhibit 10 to your deposition.
Q. And just to confirm --
MS. AHERN: Sorry. Are we on 10 or 11? We're on 11. Thank you.
Q. As a --
MR. TISI: Is this the next one?
MS. AHERN: Yeah. Hold on. I'm going to clarify it.
Q. So this photocopy that you made from Blaustein's came from the fourth edition?
A. Correct.
Q. The textbook that we have here marked as Exhibit 10.
A. (Witness nodded.)
Q. Okay. So Exhibit 11 are photocopies of specific pages from Exhibit 10, which is

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Blaustein's Pathology of the Female Genital Tract, Fourth Edition.

(Excerpt from "Blaustein's Pathology of the Female Genital Tract," Fourth Edition, marked Exhibit 11.)

BY MS. AHERN:

Q. Okay. And can you tell me, with Exhibit 11, the specific information that you found relevant to your opinions in this case?

A. Okay. So on Page --

MR. ROTMAN: You marked the copy as Exhibit 11 and the book as Exhibit 10?

MS. AHERN: Mm-hmm.

MR. ROTMAN: Okay.

A. Okay. You have to bear with me, because I don't have any highlights or anything, so I have to find it.

So Page 376, right down -- okay. The last paragraph under "Zanko Granulomatous Inflammation," it says, "Rarely, talc or another foreign substance may elicit a foreign-body reaction in the endometrium. Talc may be introduced into the endometrial cavity by instruments contaminated with talcum powder or by gloves during a pelvic examination. Patients may

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be asymptomatic or may have menorrhagia. Microscopically, the extent of the granulomatous inflammatory reaction depends on the quantity of talc inoculated. The infiltrate is characterized by histiocytes and foreign-body multinucleated giant cells surrounding the talc crystals, along with lymphocytes and plasma cells. The crystals appear as refractile, birefringent, needle-like, or fan-shaped splinters in polarizing light."

Then on Page 530 --

Q. Sorry. Let me just -- let's take this in order.

So what about that particular passage informs your causation opinions regarding talc and ovarian cancer, if at all?

A. So it is evidence that talc causes foreign-body giant cell reaction and chronic inflammation in the endometrium.

Q. And that is the uterine tissue; correct?

A. That's the lining of the uterus, correct.

Q. And how does that inform your opinions regarding the development of ovarian cancer?

A. Well, I thought, again, it's a piece of

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evidence, and it shows that talc can cause granulomatous or chronic inflammation in the female reproductive tract.

Q. And how is uterine cancer related to, for instance, high-grade serous carcinoma of the ovary?

A. Again, this is just evidence that talc can cause chronic inflammation and granulomas in the endometrium, which I think is another piece of evidence that talc can cause chronic inflammation and granulomatous inflammation in the female reproductive tract.

Q. Doctor, shouldn't talc -- based on the literature that we have available to us over the last 50 years, shouldn't talc induce that response in any tissue that it's found in?

A. Well, again, different tissues will respond in different ways, but I think it also depends -- well, I'll just...

Q. Well, as a pathologist --

MR. ROTMAN: Wait. Wait. Are you done?

MS. AHERN: Are you done?

THE WITNESS: I think so.

Q. Okay. So as an anatomic pathologist

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who knows something about granulomatous reactions, shouldn't a foreign body produce a foreign-body reaction in any tissue that it's found in?

A. Not -- no, not always. Sometimes you will have a foreign body that won't cause a foreign-body giant cell reaction. It depends on -- it depends on the particle, the foreign body, the tissue it's in. You don't always see that. And also the timing, when you're looking at it, versus how long it's been there.

Q. Well, the timing is just more or less when you observed it, not whether it occurred; correct?

MR. ROTMAN: Objection.

A. So it's hard to know whether or not it occurred -- if it had been there for a long time and you're looking years, you know, in -- years after it's been there, if you don't see a granulomatous or chronic inflammation, that's not evidence that it never occurred; it's just you're not seeing it at that moment.

Q. Do you know of any -- any foreign bodies that generate tissue-specific reactions?

A. Well, we -- I mean, we certainly have

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evidence with, say, viruses and bacteria that respond differently -- certain tissues will respond differently to different infections.

For esophageal cancer, there's some literature to suggest that very hot liquids increase your risk of esophageal cancer. So, yes, certain tissues will respond differently to different material.

Q. So my question was -- it might be just a little simpler to think of just this question -- do you know of any foreign bodies -- I'm not talking about viruses and bacteria which cause immune responses -- but foreign bodies that generate a tissue-specific foreign-body reaction?

A. Well, it's sort of semantics. I mean, viruses and bacteria -- that's why I answered the way I did -- are foreign to -- and, certainly, foreign bodies can elicit immune response. That's why you see granulomatous reactions and chronic inflammation.

So I guess I'm not -- I think I answered the question.

Q. Pathologists distinguish the different types of granulomatous inflammation based on the cause of the inflammation; correct?

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A. We look for -- if we see granulomatous inflammation in tissue, we certainly look for a potential cause. We want to rule out infection, so if we see granulomas, we'll routinely do special stains to rule out infection. Like we'll do an acid-fast Bacillus stain for microbacteria. We'll do fungal stains to rule out a fungal infection that causes inflammation.

And then, of course, if we have -- if those are negative and we're trying to figure out if there's a foreign body within a granuloma, we can use polarized light to try to find the foreign body to identify it as a foreign-body giant cell reaction.

But often you do have granulomatous inflammation and you won't find fungi -- fungal lesions -- fungal bodies or bacteria or birefringent particles on them, so you don't necessarily know why you have a granulomatous inflammation.

Q. Pathologists categorize granulomatous inflammation, don't they? They categorize it in terms of the different types of immune granulomas and the etiologic agents for those granulomas, and over here somewhere are the foreign-body

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granulomas, which are caused by talc and cornstarch and certain other inert-type materials; correct?

MR. ROTMAN: Objection.

A. Again, you can have inflammation -- granulomatous inflammation due to infection, you can have granulomatous infection -- response due to foreign bodies, and you can have granulomas in certain diseases, like sarcoidosis or Crohn's disease.

So in that respect, yes, we're categorizing granulomas, but on a daily basis, other than that type of breakdown, we're not subcategorizing granulomas.

Q. But you are aware of the literature that actually characterizes the different types of granulomas and the types of cells that are involved in the formation of those granulomas; correct?

A. As far as foreign-body giant cells and multinucleated giant cells and inflammatory versus foreign body, yes.

Q. So, you know, a granuloma caused by tuberculosis is going to be very different from a granuloma caused by talc; correct?

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MR. ROTMAN: Objection.

A. I would say not necessarily. In microbacterial infections, you can have necrosis within granulomas, but that doesn't mean that you're not necessarily going to see necrosis in a foreign-body granuloma.

Q. How often have you seen necrosis associated with a foreign-body granuloma?

A. I'd say more commonly you see necrotizing or necrotic granulomas in infectious granulomas.

Q. There are different types of macrophages that are involved, too, in foreign-body granulomas and in immune granulomas; correct?

A. As far as macrophages themselves and multinucleated giant cells that can form granulomas.

Q. There are different types, different subtypes of macrophages that are involved in --

A. Yes.

Q. -- those activities; correct?

A. Yes.

Q. Okay. So there are differences between a foreign-body granuloma and an immune granuloma?

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A. There can be.
Q. Well, there are, aren't there? I mean, there are papers that characterize these.
A. Yes, but I'm -- yes. In the literature, yes. And -- but are we necessarily categorizing them when we're looking at a particular patient? We're looking for the cause of the granuloma, but we're not necessarily subcategorizing, is my point.
Q. Understood.
Oh, I'm sorry. We were talking about the pages that you copied from Blaustein's.
What was the second page in that photocopy, Exhibit 11?
A. Okay. So Page 539.
Q. What was it on 539 that's relevant to your opinions in this case?
A. Okay. I think it starts at the very bottom. I think it carries into Page 540, where it starts talking about foreign-body reactions in the -- this is diseases of the fallopian tube.
So it starts, "Foreign material may be introduced into the tube in the course of gynecological investigation, especially hysterosalpingography, lubricant jelly, mineral

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oil, and starch and talc powder may cause lipoid or granulomatous salpingitis. Talc may cause mucosal or serosal granulomas. Examination of all granulomas or foreign-body reactions under polarized light is useful in the recognition of these processes."
So, again, I'm just referencing the fact that talc can cause granulomatous reaction in the fallopian tube.
Q. So another tissue that's exposed to talc forms the typical type of foreign-body response?
A. That can form a granulomatous reaction.
Q. Okay. And does that in any way inform your opinions on causation, other than granulomatous reactions occur?
A. Well, so, again, it's another piece of evidence that talc can cause a granulomatous reaction within the female reproductive tract.
Now, the fallopian tube, we know some -- has been indicated as a precursor site for certain high-grade serous carcinomas, so I think it's relevant.
But, again, you know, we're talking about mechanisms that talc may eventually cause ovarian

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cancer, which is sort of the plausibility arm of the Bradford Hill. I think it's compelling evidence that we see that you can get granulomatous inflammation and some of these sections have mentioned lymphocytes and plasma cells in the tissue. I mean, I think it's a further piece of evidence that talc can cause these -- this type of inflammation in female reproductive market.
Q. How often have you, in your career, seen a talc granuloma in gynecologic specimens?
A. We don't routinely do -- perform polarized light microscopy on ovarian tumors, partly because you really need electron microscopy. You can -- with polarized light microscopy, you can tell that there's a foreign substance there, but that's pretty much as far as you can -- you can get. You need more testing to be able to determine what type of particle it is, usually. So we don't, in daily practice, routinely use polarized light microscopy.
Now, it's entirely possible that, you know, in the course of my career, I've come across chronic inflammation or granulomas in an ovarian tumor that could have been due to talc that I

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didn't polarize so I didn't see particles, I guess.
Q. So let me back up and just ask you: How often in your career have you seen foreign-body granulomas? Regardless of whether you've identified the particle in the granuloma, how often have you seen foreign-body granulomas in gynecologic specimens? Not just tumors, but any gynecologic specimens you've reviewed.
A. No, I understand.
Q. Okay.
A. You can certainly see granulomas -- how often, I can't give you a number; that would just be wildly guessing -- but you can see granulomas in the endometrium. You can see them in different types of tumor.
Sometimes it's -- you'll see granulomas, but you won't see a particle, so you don't know for sure if it's a foreign-body granuloma; you just see the granuloma because you're not using polarized light microscopy on it.
MR. KLATT: Object. Nonresponsive.
MS. AHERN: Same.
Q. So how often, though, in your career -- you can give me an estimate -- have you seen

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foreign-body granulomas in gynecologic specimens?
MR. ROTMAN: Objection.
Q. I'm not talking about immune granulomas, but just foreign-body granulomas. We'll start there.
MR. ROTMAN: Objection. You've asked that question. She's answered it.
A. So, again, I've seen granulomas in my career in the female reproductive tract, but I don't -- pathologists don't routinely use polarized light microscopy in that instance to look for foreign bodies.
Q. Okay. So are you done?
MR. ROTMAN: Can we take a break?
MS. AHERN: Not just yet. Let me finish this line of questioning and then we can take a break. Because we may want to -- what time is it?
MR. ROTMAN: It's been an hour.
MS. AHERN: 11:30. If we go a little bit longer, we can break for lunch if you want.
MR. ROTMAN: I just want to take a break in the next few minutes.
MS. AHERN: Sure.

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BY MS. AHERN:
Q. Doctor, are you able, as a -- as a pathologist, under regular light microscopy to identify a foreign-body granuloma? Not the content, just the foreign-body granuloma.
A. I would say it depends on the specific granuloma. Sometimes, for example, in epidermal inclusion cysts, you can see the keratin under light microscopy that's causing the reaction, but you don't always -- you won't always necessarily see a particle. They're very small. And unless you're looking specifically for polarizable birefringent particles, you're not going to see it just with regular light microscopy.
Q. So my question wasn't -- and I thought I was specific -- my question wasn't whether or not you could see the particle; my question was: You should be able to see the foreign-body response in terms of multinucleated giant cells.
Do you -- can you see that under regular light microscopy?
A. Well, so you're categorizing it as a foreign-body granuloma. What I'm saying is you can see granulomas, of course, under light microscopy. But if you're not looking for a

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foreign body, you're not necessarily going to be able to say whether or not it's a foreign-body granuloma with absolute certainty unless you're looking under polarized light microscopy. And even then, you might not see it under polarized light microscopy, because it depends on the section of the tissue you're looking at and --
Q. Okay. Thank you.
And if you see a foreign-body response in tissue, do you then go one step further and polarize to see if you can identify whether that's got a foreign body in it?
A. It certainly depends on the situation.
So, for example, in cases where there's been a surgery and they've taken out more tissue after surgery, you might be looking for polarizable foreign body. Often, you can see a suture on light microscopy. But, yeah, we do -- depending on the situation, we will use polarized light microscopy to find foreign bodies.
MR. ROTMAN: Okay.
Q. How often do you polarize specimens where you've found a foreign-body response? How often do you do that?
A. I think -- I think I tried to come up

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with an estimate. I think I have it in my report, actually, in the beginning.
Yes. So I estimated that I use polarized light microscopy for this purpose, which is identifying foreign material to explain an inflammatory reaction, I estimated about twice a month. It's an estimate.
And I -- well, that was -- actually, I was referring to calcium oxalate crystals in breast biopsies. That's different. So it's not uncommon, let's put it that way, but I can't really give you a -- an estimate.
Q. What was the estimate for breast tissue?
A. I think it was twice a month, is what I said.
Q. So compared to looking for calcium crystals in breast tissue twice a month, how often in gynecologic specimens do you look for foreign bodies?
A. I would say slightly less than that.
Q. Maybe once a month, maybe less than that?
A. Once a month is probably a good estimate, I guess.

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Q. Do you know, based on your review of the epidemiologic literature, what proportion of women are said to use talc?
A. I believe I've seen in some of the literature -- it depends on the population, I think. I think I saw -- well, again, I'd have to pull out the papers to be absolutely certain, but I remember there was a reference to African-American women, about 50 percent of them using talc.
Q. Would you say that in 50 percent of the gynecologic specimens you review, you find foreign-body granulomas or granulomas?
A. Well, I wouldn't necessarily expect -- I wouldn't expect to, just because, you know, again, we're looking at an ovarian tumor at a very particular point in time.
How many granulomas -- how much talc is getting to the ovary, we don't -- we don't know how much talc is getting to the ovary. We know it's been found there, we know it can get there, but we don't know with how much use, how much is actually getting there.
So we wouldn't necessarily find a lot of granulomas in ovarian tissue of women that use

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it, because we don't know exactly how much is getting there or we don't know how long those granulomas are there once the tissue is in the ovary.
I mean, 20 years later, when you're looking at the -- at the ovary for a talc particle that's been there, we don't know if the granuloma would still be there or the chronic inflammation would still be there.
Q. And my question wasn't specific to ovarian tissue; it was just gynecologic specimens.
Because you review more than ovarian tissues when you're looking at gynecologic samples; correct?
A. Yes.
Q. So looking at all of your gynecologic specimens, your vaginal, vulvar, endometrial, tubal, ovarian, I guess omentum might fall in there, how often do you identify foreign bodies or foreign-body granulomas?
A. I would have to be -- a completely ballpark guess, but, I don't know, maybe every -- I'm really trying to figure out a somewhat ballpark figure. It's tough.

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I mean, it's not -- it's not frequent that you're going to find foreign-body giant cell reactions in tissue, but, again, it doesn't mean that they weren't there. Maybe --
Q. And this is based just on your experience. I know that -- I don't want you to guess about what might have been there --
A. Yeah, I'm --
Q. -- but based on your experience as a practicing pathologist.
A. It would just be a pure guess at this point. I couldn't give you an accurate number.
Q. Do you see foreign-body reactions in 50 percent of the gynecologic specimens or cases that you review?
MR. ROTMAN: Objection.
A. I would say it's less than 50 percent.
Q. Is it less than 25?
A. I would say less than 25.
Q. Less than ten?
A. Probably less than ten.
Q. Less than five?
A. That's where I'm not exactly sure.
Q. Okay.
MS. AHERN: All right. We can go ahead

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and take a break. Thank you.
THE VIDEOGRAPHER: Here ends Media 2. Off the record, 11:44 a.m.
(A recess was taken.)
THE VIDEOGRAPHER: Here begins Media No. 3 in today's deposition of Sarah Kane, M.D. Back on the record, 12:02 p.m.
BY MS. AHERN:
Q. All right. Doctor, can we go ahead and keep moving through that photocopy, Exhibit 11.
Can you tell me what the next page was?
A. Okay. We just read from Page 540, I believe, so the next one is Page 648.
Q. Okay. And tell me what on 648 caught your eye.
A. Okay. It's the first paragraph under "Noninfectious Granulomatous Peritonitis." So it says, "Foreign material typically recognizable on histologic examination can elicit a granulomatous reaction on the peritoneum. Starch granulomas from surgical gloves, douche fluid, and lubricants typically incite a granulomatous and fibrosing peritonitis. In occasional cases, the inflammatory reaction may be a tuberculoid type with KCS necrosis. The periodic acid shift (PAS)

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positive starch granules exhibit the characteristic Maltese cross configuration" --

THE COURT REPORTER: I'm sorry, you're reading too fast.

THE WITNESS: I'm sorry.

A. "The periodic acid shift (PAS) positive starch granules exhibits a characteristic Maltese cross configuration under polarized light. Talc was once an important cause of granulomatous and fibrosing peritonitis because of its use as a lubricant on surgical gloves and talc-induced peritonitis has been described more recently in drug abusers." I think that's kind of where it stops.

Q. Okay. And how does that passage that you just read inform your opinions in this case?

A. Well, again, it's just another -- similar to the last pieces, this is the peritoneum, so this is outside of the fallopian tube. Once particles are outside of the fallopian tube, they are in the peritoneum. That's where the ovary is. And so it's discussing foreign-body granulomatous reactions in the peritoneum.

Q. And this question -- this passage that

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you just read also mentions that starch granules from surgical gloves --

A. Yes.

Q. -- cause granulomatous and fibrosing peritonitis, which is the same that they mention talc use to.

Would you say that starch granules, then, have the capacity to cause chronic inflammation that can lead to cancer?

A. Starch can cause inflammatory reactions, but it's a -- very different, in that it's bioabsorbable, and so the particles are absorbed in the body. And the literature hasn't supported a link between starch and ovarian cancer.

Q. How many studies have evaluated the association between starch and ovarian cancer?

A. I couldn't say, off the top of my head, how many. But I know, you know, they looked at starch when they were evaluating whether or not to remove it from surgical gloves, and they ended up deciding to remove it from surgical gloves.

And I -- I think at that point they had done a literature search. I don't think there was -- I don't know how many studies off the top of my

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head.

Q. And when you say "they" were looking at, are you talking -- who are you talking about?

A. When the -- when the regulatory -- if I recall -- did I put that in my report? -- they removed -- I know that they removed starch from surgical gloves because it was causing an inflammatory reaction.

And they had started using starch more commonly because talc had been removed from surgical gloves for also causing inflammatory reactions.

Q. And talc particles and cornstarch particles cause the same foreign-body reaction in the peritoneum and fibrosis; correct?

A. Well, again, they can cause a granulomatous reaction, but they're bioabsorbable, so it's not going to be -- you know, when we're talking about talc, we're talking about the talc in surgical gloves. And, you know, talc is not bioabsorbable and it will stay in the peritoneum longer than starch, which is bioabsorbable. So it will -- the inflammation will likely resolve more quickly. It's a different -- it's a different type of reaction

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because it's bioabsorbable.

Q. Well, they both cause granulomas; right?

A. Mm-hmm.

Q. And they both cause fibrosis; correct?

A. They can cause fibrosis.

Q. Does the biodurability of the causative agent determine how long fibrosis exists?

A. Well, the fibrosis is thought to arise from the inflammatory process. And since -- I don't know how much data is really there except to say that starch is bioabsorbable and talc is not. So talc is going to be available for an inflammatory response more than a starch particle will.

Q. Is the purpose of a foreign-body granuloma to essentially wall off an irritant, a foreign body, from the rest of the tissue to prevent damage?

A. That can be one reason.

Another reason is if the particle is large enough and one macrophage can't handle it because of its size, it will sort of recruit more macrophages to the area to try to digest the foreign material, which is not going to -- they

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won't be able to digest the talc particle.
Q. If they can't digest the particle, these macrophages will fuse to form a multinucleated giant cell and surround the particle to basically encapsulate it and prevent it from harming the surrounding tissue; correct?
A. It's possible that they would, yes, they would recruit more macrophages and potentially do that.
Q. Isn't that the purpose of a foreign-body granuloma?
A. So, again, you can get well-formed -- you can get well-formed encapsulated granulomas. You can also get sort of poorly formed granulomas that are -- when more macrophages have been recruited to that site.
You can get a -- you can get a histiocytic reaction that isn't a well-formed granuloma in the sense that you're talking about, where it's kind of walling off the foreign body. You can get histiocytic reactions that aren't as well formed like that.
Q. But we're just talking about the actual granuloma itself, those particles that do result in a well-formed granuloma.

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Once that granuloma has formed, it can persist for many years, can't it, without damaging the surrounding tissue?
MR. ROTMAN: Objection.
A. I think it would depend. Macrophages have a certain lifespan, so it's going to be constantly recruiting different macrophages to that site.
So I don't think we can say for certain that the -- in fact, I think the body is still reacting to that foreign body if it's still recruiting new macrophages in.
Q. Do you know that for a fact based on your reading of the literature of granulomas, that that's the mechanism behind a foreign-body granuloma, as opposed to an immune granuloma?
A. What I'm saying is -- is that macrophages have a certain shelf life, and so they will constantly recruit new macrophages to that area.
Now, whether or not there's an exposure in that particle while it's in that process, I don't think we can definitively say.
Q. Can you cite to any papers that support your understanding of that process whereby

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macrophages are continuously recruited to foreign-body granulomas?
A. I know that I've read it in the course of my daily practice. I can search at some point for it, but I know that that's the case, because I know that macrophages, again, have a certain lifespan.
But, you know, again, the inflammatory response, we also don't know how long that inflammatory response is going to be there for sure. Is it possible that at some point the granuloma resolves and you get some fibrosis and the talc particle or whatever particle is there remains? I think that's possible and likely, in fact, because you do see resolution of granulomas with fibrosis.
Q. Is fibrosis associated with the development of ovarian cancer?
A. There hasn't -- there hasn't been a lot -- again, the causes of ovarian cancer are sort of -- the literature and the research is still bearing all of it out, but from what I know of the literature, I don't think that they found fibrosis itself being an increased risk factor for ovarian cancer.

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Q. Is fibrosis associated with chronic inflammation?
A. It can be, yeah. Chronic inflammation can lead to fibrosis.
Q. Do you know of any literature that has linked talc granulomas introduced into the body through the use of talc-dusted surgical gloves with any sort of cancer?
A. So we know that talc can -- there are studies that have shown talc in the ovaries, and we know that chronic inflammation has been implicated in cancer.
So if talc can reach the ovaries -- and we also have evidence that talc causes chronic inflammation. So if talc reaches the ovary, I think it's a plausible mechanism for talc from surgical gloves to cause an inflammatory reaction and lead to cancer. I think that's plausible.
And, again, that's the plausibility arm of it. You know, that's a piece of the general causation opinion, but, you know, they're still piecing together a lot of the etiology of ovarian cancer.
Q. Then why --
MR. KLATT: Objection, nonresponsive.

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MS. AHERN: Nonresponsive, yeah.
Q. Doctor, why are you so sure, then, that talc causes ovarian cancer?
A. It's --
MR. ROTMAN: Objection.
A. So I can lay out to you my methodology. It's in the report. I did very in-depth, extensive review of the literature, which included the epi studies, animal studies, and biologic studies.
And I think -- well, I know that the epi studies have been very consistent with the increased risk associated with talcum powder product usage -- I'm talking about talcum powder product, what's in the bottle -- and perineal talc application with ovarian cancer.
And I think if you're looking at -- if you go through the methodology that I used and you're looking at the Bradford Hill analysis, which I've laid out in the report, I've come to the professional -- you know, my professional judgment is that the talcum powder products -- weighing everything, that talcum powder products cause ovarian cancer.
And I know -- and, interestingly, about

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three weeks after I wrote my report, there was the Health Canada report that, in reading their methodology and the literature that they reviewed, was very similar to what I reviewed and my methodology. And they came to the same conclusion.
MR. KLATT: Objection.
MS. AHERN: Objection. Nonresponsive.
Q. Doctor, my question was: Do you know of any literature that has linked -- sorry.
My first question we're going to go back to now is: Do you know of any literature that has linked talc granulomas introduced into the body through the use of talc-dusted surgical gloves to any sort of cancer?
MR. ROTMAN: Objection.
MS. AHERN: What's the objection?
MR. ROTMAN: Your question was --
MS. AHERN: I'm reading it.
MR. ROTMAN: -- why are you so certain.
MS. AHERN: Well, I just told you we're going back to this question.
MR. ROTMAN: Okay. So you're asking -- you're not saying that she didn't -- you're not repeating your former question?

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MS. AHERN: No. We're going back to this question.
MR. ROTMAN: Okay. That's fine.
So you're asking her again a question that she previously answered.
MR. KLATT: No --
MS. AHERN: I'm interested in --
MR. KLATT: -- a question she didn't answer.
MS. AHERN: -- the question she didn't answer first.
BY MS. AHERN:
Q. Which is: "Do you know of any literature that has linked talc granulomas introduced into the body through the use of talc-dusted surgical gloves with any sort of cancer?"
Do you know or not know of any literature that supports that?
A. Well, first of all, I think we're talking about -- you're talking about surgical glove talc, right, which is pharmaceutical-grade talc, which is different from the talcum powder product that I'm opining about.
And we know that these talc particles can

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get to the ovary and we know that talc can cause chronic inflammation.
Q. Doctor, first question about your answer is: What makes you think that cosmetic talc used in Johnson & Johnson baby powder is not pharmaceutical-grade talc?
A. I'm talking about the product, the ultimate product.
Q. Johnson's baby powder; correct?
A. Whatever is in the bottle.
Q. You're saying that's not pharmaceutical-grade talc?
A. Whatever is in the bottle.
Q. Okay.
A. So --
Q. What is your -- what is your understanding of what pharmaceutical-grade talc is and how is that different from what's in Johnson's baby powder?
A. So I didn't opine on the constituents of the talcum powder that -- the baby product -- talcum powder products, the Johnson & Johnson. I saw evidence as to what's in the talcum powder products, but I didn't do my own analysis as to what is in the talcum powder products.

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But pharmaceutical-grade talc, if we're talking about talc that's used in pleurodesis, for example, is going to be different than talcum powder products in the bottle --

Q. Okay.

A. -- cosmetic talcum powder products.

Q. So how is it different?

A. So, again, I didn't do my own analysis as to what is in the talcum powder product, but that's what I am -- that's what my general causation opinion is on, is the talcum powder product in the bottle, that regular perineal use of that causes ovarian cancer.

Q. My question to you is: What do you understand the difference between the talcum powder products and pharmaceutical-grade talc --

MR. ROTMAN: Objection.

Q. -- to be?

A. So I've seen evidence that in talcum powder products, there are heavy metals. There are fragrances that are added to the talcum powder product that, in talc used for pleurodesis, they wouldn't be adding fragrances to that type of talc.

Q. Would -- you're not saying that talcum

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powder products that are sold to consumers have been altered to add heavy metals, are you?

A. Well, I've seen the report of Dr. Crowley that looks at heavy metals and fragrances in the talc, the baby product talc powder that he examined. I did not do my own analysis of that.

Q. Does pharmaceutical-grade talcum powder also have associated metals and sometimes heavy metals?

A. I'm not sure if I've seen data as to what is specifically in pharmaceutical-grade talcum powder, but, again, to me, what is important is the ultimate product and what is in that bottle. It can -- whether it's platy talc, fibrous talc, asbestos, heavy metals, fragrance metals.

I mean, to me -- you know, I've seen evidence of those things in that product, but to me, what I'm looking at is the final product when it comes to causing ovarian cancer.

Q. So what is different about that final product and pharmaceutical-grade talc? What specific components have been added to that that affect your opinions in this case?

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A. Well, I think I've answered, like, to me, it doesn't -- it doesn't really matter what -- the difference between pharmaceutical talc and talcum powder products; it's whatever is in that talcum powder products -- product, whatever is in the bottle that women are buying off the shelf and applying to their perineum.

MR. KLATT: Objection. Nonresponsive.

MS. AHERN: Objection. Nonresponsive.

Q. My question was -- originally was: Do you know of any literature that connects talc dust of surgical gloves and any sort of cancer.

And then you said, "First of all, I think we're talking about surgical glove talc, which is a pharmaceutical-grade talc, which is different from the talcum powder product that I'm opining about."

So what I'm asking you is: What is different about the talcum powder product that you're --

A. It's what I'm opining about. You know, I haven't --

Q. Right.

A. -- looked at the talc that's used for pleurodesis, for example. It's what I'm

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separating out.

I've looked at the talcum powder product that women use on their perineum, what they bought off the shelf. I haven't looked at pharmaceutical-grade -- let me correct that -- pleurodesis talc, for example. I have not looked at pleurodesis talc and ovarian cancer. I have not looked at any literature specifically on that. It's been the talcum powder products that women are buying off the shelf and using on their perineum.

Q. So if I told you that Johnson's baby powder starts out as pharmaceutical-grade talc and that, beyond that, fragrance is added, would it be the fragrance that you're taking issue with that you believe is causally associated with the development of ovarian cancer?

A. Again, I -- it's whatever is in that bottle. It could be platy talc, fibrous talc, asbestos, heavy metals, fragrance. It -- to me, it's the product, whatever the product is that they are using.

Q. And you have done a biologic plausibility analysis for fragrances, for metals, for asbestos, for fibrous talc, and for platy

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talc --
A. So --
Q. -- each one of those constituents?
A. So I have looked at evidence -- so Dr. Crowley's report, I mentioned. I've looked at Dr. Longo's report. I've looked at Hopkins and the Pier charts from their depositions. I'm aware of evidence that these heavy metals and fragrances and asbestos are in there.
However, I haven't done -- what I know, I looked at the -- I've looked at some literature and I've looked at the IARC categorization of the heavy metals. I've looked at Dr. Crowley's report and I've done an extensive look at asbestos and ovarian cancer.
But, ultimately, those are just pieces of biological plausibility. What I'm mainly -- what I am opining about is the ultimate product. And, again, it can be platy talc, it can be fibrous talc, it can be asbestos, it can be heavy metals.
It's pieces of information that strengthen the plausibility. We know that asbestos causes ovarian cancer, that certain heavy metals are carcinogens, which the IARC categorized them as. So it's just -- it's just additional pieces of

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information that strengthen the biological plausibility arm of it.
Q. Doctor, how do you arrive at a causation conclusion without a well-defined agent of exposure?
MR. ROTMAN: Objection.
Q. Do you understand what I'm asking you? How do you arrive at your causation and conclusion when you're not sure what it is about the talcum powder products that's actually biologically relevant?
A. Well, I think -- well, strike that.
The epi studies are looking at the product that the women are using. So that is the agent. It's the -- it's the total product. That is the agent.
So when you're looking through -- let me just -- so let's keep in mind that we're looking at that product.
And then if you go through my Bradford Hill analysis, you look at strength of association. And, overall, there's a consistent relative risk that's between 1 and 2. I would say it's, across studies, averaging 1.3 to 1.4 relative risk, and that's consistent across studies. That's the

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consistency piece of it.
Q. Can I ask you -- you can go through all of it if you want, but would you rather break it down piece by piece?
MR. ROTMAN: She should answer your question.
MS. AHERN: I'm not sure she's answering my question. My question was: How do you come up with causation when you don't know what the exposure is?
MR. ROTMAN: I think she's answering the question.
MR. TISI: That wasn't the question. The question was: Do you need to know the agent? And she said the agent is the product.
BY MS. AHERN:
Q. The agent is everything in it?
A. Yes, the agent is whatever is in that talcum powder product.
Q. So are you basing, then, your causation conclusions on the epidemiologic literature alone?
A. The epidemiologic literature is very comp- --
MR. ROTMAN: She was not done with her

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earlier answer. Now you've gone two more beyond it.
MS. AHERN: She's answering. Why don't you let her answer. If she wants to go back, she can.
MR. ROTMAN: No, I want her to go back. She was -- she was in the middle of going through her Bradford Hill to answer your earlier question and you cut her off. So she had covered strength of association.
BY MS. AHERN:
Q. Doctor, you can answer the question the way you want to answer the question.
MR. ROTMAN: Now there's no question in front of her.
MS. AHERN: Well, because you interrupted it.
MR. ROTMAN: Let's go back to what the question was before you cut her off. "Do you understand what I'm asking you? How do you arrive at your causation and conclusion when you're not sure what it is about the talcum powder products that actually biologically -- that are biologically relevant?"
And then you gave -- then you started

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an answer about the epi studies are looking at the product that the women are using, and you were talking about strength of association and then you said, "And that's consistent across studies. That's the consistency piece of it," and then you were interrupted.

So were you done with your answer to that earlier question?

THE WITNESS: I can continue, because I think it's important.

I mean, I was -- my general causation opinion, the methodology I used was to answer the question: Does perineal application of talcum powder products, the, you know, baby powder product that you buy off the shelf, does that cause ovarian cancer? So it's whatever is in that bottle.

So with the methodology that I used, looking at the epi data, but also considering the Bradford Hill criteria -- which, you know, looking for specificity is another one. So most of the studies showed a stronger -- a strong association with serous ovarian cancer, but it was basically associated with epithelial ovarian cancer, so all groups of epithelial ovarian

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cancer. It was pretty specific, the epi data, for that type of ovarian cancer.

Temporality. If you look at that, I mean, the case-control studies are retrospective reviews, so we know that they were using talc before their diagnosis of ovarian cancer.

Biological gradient. For those studies that looked at a biological gradient, there was an evident -- there was evidence of a dose-response, not all of the times statistically significant, but the trend -- you can see a trend of a dose-response across studies.

And then we get into the plausibility piece, which you've been discussing mostly so far in this deposition, which has to do with the plausible mechanism of talcum powder -- what I'm thinking of, talcum powder products -- whatever is in that bottle was what I'm looking at -- talcum powder products causing -- the plausibility of it causing a chronic inflammatory response, leading to ovarian cancer. We've been discussing that quite a bit today.

And then coherence. So I can refer again to my report. Coherence, in this context, means coherence between epidemiologic and

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generally accepted knowledge of the disease in question.

So we know that particles can reach the ovary. We know that talc can cause chronic inflammation. We know that chronic inflammation is associated with certain types of cancer. We know that certain types of ovarian cancer have shown association with chronic inflammatory conditions.

So, again, going through all this is experiment and analogy, experiment with the animal studies and the in vitro studies. And analogy, I used the example of asbestos, because even though asbestos is -- you know, asbestos is chemically similar, you can have asbestos fibers and talc fibers, but it's a similar mineral chemically, and we know that that is a carcinogen. So that's part of the analogy.

But, again, it's the whole picture. I mean, you look at the -- all of this data following my methodology and you apply the Bradford Hill criteria guidelines -- the Bradford Hill guidelines. And, looking at all that, my professional judgment is that the talcum powder products can cause ovarian cancer.

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Q. Okay. Are you done? I don't want to interrupt you.

A. I think I answered the question.

Q. Okay. One of the things, and I guess a major component of the talcum powder products, would be talc; correct?

A. Presumably -- it's called talcum powder, so presumably, talc would be a constituent.

Q. Do you know what percentage of talcum powder products is talc?

A. Again, I did not do my own analysis as to how much talc was in that product.

Q. Do you know whether any of the heavy metals that you looked at or were examined by other experts in this litigation, whether any of those are known carcinogens for the ovary?

A. So it's another piece of information. There is not, to my knowledge -- looking at what the IARC looked at, there's not data right now on those heavy metals and ovarian cancer, but it's -- it's a -- it's a piece of the puzzle. It's a piece of information.

The IARC has called some of them carcinogenic, some of them probably carcinogenic,

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so we know that they can cause cancer. And if they're in the talcum powder products, then it's just another piece to the puzzle of plausibility.

Q. Are you saying that the probably carcinogenic category for IARC means that they can cause cancer?

A. Well, we can look at what the IARC 2A categorization -- category actually says, what they break it down. But my understanding is it's -- probably carcinogenic means it probably causes cancer, more likely than not, probably causes cancer.

Q. How many categories does IARC have?

A. They have four.

Q. What is the -- what is Category 1?

A. Carcinogenic.

Q. Known to be carcinogenic?

A. Mm-hmm.

Q. And then the next?

A. Probably carcinogenic.

Q. And then?

A. Possibly carcinogenic.

Q. And then?

A. I think it's unclassifiable. I have to look. But I think it's uncertain, basically.

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Q. And then what is the last?

A. And then known not to be carcinogenic.

Q. How many agents are in the known not to be carcinogenic category?

A. Very, very few.

Q. One; right?

A. That's plausible. I haven't looked at the list recently.

Q. So going back to the major component, you don't know what percentage of talcum powder products are actually talc?

MR. ROTMAN: Objection.

A. I have not done my own analysis as to what the components are of that talcum powder -- of the talcum powder products.

Q. Do you agree that carcinogens can be organ specific?

A. I will agree that certain tissues respond to certain things differently.

Q. Do you agree that carcinogens can be organ specific?

A. Certain tissues respond to certain things differently. If you're casting that wide a net to say that one specific carcinogen only causes one type of cancer, I think that's a

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little too wide a net. I think science is always evolving and there's always the possibility of an unknown cause of a certain type of cancer.

MS. AHERN: Objection. Nonresponsive.

Q. My question was just: Can carcinogens be organ specific?

A. And I feel like I answered that fairly.

Q. Do you know of carcinogens that are organ specific?

A. I know -- for example, we know that H. Pylori causes increased risk of gastric cancer, but not oral or esophageal cancer.

We know that HPV infection can cause cervical cancer, anal cancer, certain types of squamous cell carcinomas of the oropharyngeal system, but not, you know, of the endometrium, for example.

So we know that certain things cause certain cancers and aren't -- haven't been associated with other types of cancers. But to cast that wide a net, to say that a carcinogen is only going to cause one type of cancer or this cancer is caused only by this carcinogen, I think that's too wide a net, because I feel like research is constantly evolving. We're constantly learning

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of new causal factors in cancer.

Q. Do you think that dose is an important consideration when you're looking at the toxicologic effects of an agent on a tissue?

A. I think it is a piece of information. I'm looking at my biological gradient portion of my report, and I said in my report that it was an important factor in my analysis because it does add information to the overall causality.

Q. Are there agents that can be toxic at certain levels and not toxic at other levels?

A. There are certainly agents that are more toxic with increased exposure and increased duration. We don't know all of the thresholds for carcinogenicity of all carcinogens.

Q. As part of the biologic plausibility analysis that you would do on a particular agent, would that take into consideration the relative levels of exposure that a person would have to that agent?

A. Well, dose-response -- I -- I'm taking it -- your question -- can you rephrase the question? I'm sorry. I just want to make sure I'm answering it accurately.

Q. To determine whether it's biologically

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plausible for a particular agent to cause a particular harm, would you need to be able to characterize the dose of that agent that is required to elicit the effect that you're looking for?

A. I think it's a piece of the information -- a piece of information, but you're not always going to be able to determine a dose-response. It's going to depend on the carcinogen, the agent, the routes of exposure. You're just not always going to have that data, unfortunately. It would be nice to have, but you're not always going to have it, and you don't necessarily have to have it to come to plausibility.

Q. And do you have well-characterized levels of exposure to the ovaries for women who are using talc perineally?

MR. ROTMAN: Objection.

A. So some of the -- we're never really going to be able to figure out what an actual -- to characterize what an actual dose -- dose of talcum powder product of what -- of a talcum powder product in a particular use. We don't know how much a woman is putting on her hand to

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place into the perineum. We don't know how much of that product is getting to the ovary. We know that it can get to the ovary because we've seen talc in the ovary. But where -- it's extremely difficult in this type of situation, when women use the product differently, to know what the dose -- what a single dose is.

Now, if you're talking long-term, frequent use of talcum powder products, of course, the exposure is going to be greater than a single use of that product.

But are we ever going to know what one dose of talcum powder product is? I don't think we're going to be able to say that and how much of one dose reaches the ovary.

But, certainly, again, with -- over time, increased frequency and duration, it's -- you know, more of that product is going to reach the ovary.

Q. So going back to the discussion we had earlier about surgical glove talc, do you know of any literature that links exposure to talcum powder -- pharmaceutical-grade talcum powder from surgical gloves to any kind of cancer?

A. I did not opine on surgical glove talc

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and ovarian cancer. I certainly saw some of the data about talc migration and cornstarch on surgical gloves migration, but I didn't specifically -- I don't know if -- I don't even know if that study has really been done.

Q. Did you consider the publications on talc responses -- or, excuse me, did you consider the publications on granulomatous reactions to talc from surgical gloves to be relevant to your biologic plausibility analysis?

A. It's a piece of information that talc -- now, again, surgical glove talc, for me, is different than the talcum powder products.

You know, my general causation opinion -- I just want to be clear -- is about, you know, talcum powder products, not the talc used in pleurodesis, not talc on surgical gloves.

Having said that, I think it's an important piece of information to know that talc on surgical gloves can cause a granulomatous reaction, because that is further evidence for plausibility that talcum powder products -- they're called talcum powder products, so, again, it's sort of an assumption. It doesn't really matter to me what's in there, but my assumption

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is that whatever -- the talc or whatever is in that product is causing the -- a chronic inflammation. And so it's part -- it's a piece of evidence for the plausibility.

Q. So are you not aware of any studies, based on the review that you did conduct, that link surgical glove talcum powder with the development of any cancer?

MR. ROTMAN: Objection.

A. So I'm not sure how you could do that. If you're looking at patients who -- I think that would be a very difficult study to design.

If you're looking at women -- if you're doing a case-control study -- I'm just thinking -- and you're looking at patients who have been diagnosed with ovarian cancer who have, at any time, had surgery during the time period that talc was used on surgical gloves, I think that would be a difficult study.

Q. My question to you was --

MR. KLATT: Objection. Nonresponsive.

Q. My question to you was: Are you aware of any studies or literature that link talc-dusted surgical gloves to the development of any kind of cancer?

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MR. ROTMAN: Objection.
THE WITNESS: My thing is not --
MR. ROTMAN: There's a button you can push.
THE WITNESS: Oh, "follow."
MR. ROTMAN: Do you see the button that's flashing on the right-hand --
THE WITNESS: Yeah.
MR. ROTMAN: -- side? If you hit that, it should go to the bottom.
THE WITNESS: Okay. I see. Yup.
MS. AHERN: And I'll withdraw that, because there's -- the question asked first was, I think, better. I slightly modified it on accident.
BY MS. AHERN:
Q. Are you aware of any studies, based on your review, that link surgical glove talcum powder with the development of any kind of cancer?
And, Doctor, to be clear, I'm only interested in whether you know of a study, not whether one could be conducted.
A. Off the top of my head, it's possible that one exists, but I can't come up with one off

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the top of my head.
Q. Do you know of any data linking surgical glove talcum powder with the development of any cancer?
MR. ROTMAN: Objection.
A. It would be my same answer.
Q. That you don't know, but there might be?
A. Sitting here right now, I can't come up with a specific study that evaluated ovarian cancer patients who have had surgery with talcum powder gloves.
Q. Any cancer. Not ovarian cancer, any cancer.
A. Similar. Sitting here right now, I cannot think of one off the top of my head.
Q. And wouldn't that have been something you think you would have picked up in your review?
A. It's possible that I did. I just said I can't think of it off the top of my head. It's possible that I did at some point.
But my -- and, again, I tried to make every effort to be able to identify studies and literature and evidence that were relevant or

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could be helpful information to my general causation opinion. So it's possible that I did.
Q. Is it in your report or cited in any of your reference lists?
A. Again, I can look through my whole reference list. It's the same answer. Off the top of my head, I don't know the answer to that.
Q. Do you know of any studies or any data that link foreign-body granulomas to the development of any kind of cancer?
A. Well, we know that asbestos can cause a granulomatous reaction and asbestos is certainly associated with mesothelioma and lung cancer.
Q. Are there other biologic properties of asbestos that contribute to its carcinogenicity?
A. It can provoke a reactive oxygen species inflammatory response.
Q. Can it disrupt DNA?
A. It can based on that mechanism, yes.
Q. Have you seen any studies or data suggesting that talcum powder can do those things?
A. I've seen studies that show that talcum powder can increase production of reactive oxygen species and can change gene expression in

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mesothelial cells. So, yes, I mean -- let me go back to your question.
So I would say, yes, there are studies that show talc can cause the production of reactive oxygen species and reactive nitrogen species, which can disrupt DNA, similar to asbestos.
Q. How do reactive oxygen and nitrogen species disrupt DNA similar to asbestos?
A. Well, it's the reactive oxygen species -- it's part of this feedback loop with -- what's the word I'm looking for? -- tumor factors like COX and TNF alpha. It's related to those types of expressions and an inflammatory response.
Q. Are you relying on cell studies?
MR. ROTMAN: Objection.
A. I have looked at cell studies. The Buz'Zard study is one, and I know Saed has done a lot with myeloperoxidase and ovarian cells. He recently came out with a paper.
So it's, again, a piece of information towards the plausibility arm of my general causation opinion.
Q. Have you seen any studies in animals or in humans that have linked the specific enzymes that Dr. Saed has evaluated in cell studies to

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the development of ovarian cancer?
A. So there have been some studies that have looked at anti-inflammatory drugs, aspirin and NSAIDs in particular.
The data on NSAIDs has been less consistent, but the data on aspirin has been consistent, in that it lowers the risk of ovarian cancer with regular aspirin use.
And aspirin, one of the mechanisms of action is on the cyclooxygenase expression, which is similar to the cyclooxygenase expression seen in some of the in vitro studies.
Q. So my question was: Have you seen any studies in animals or in humans that have linked specific enzymes that Dr. Saed has evaluated in his cell studies to the development of ovarian cancer?
MR. ROTMAN: Objection.
Q. Are you relying, then, on epidemiologic studies looking at NSAID and aspirin use?
MR. ROTMAN: Objection.
A. I'm saying that the NSAID and aspirin use is another piece of information that -- as to plausibility, mechanism -- and mechanism of regulation of pathways that can result in

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reactive oxygen species and cause an inflammatory response.
MR. KLATT: Objection. Nonresponsive.
MS. AHERN: Same.
Q. Let's go back to that. We'll finish up this Exhibit 11.
What was the next page, if any, the last page in your photocopy?
A. Okay. So this is Page 1216 of the fourth edition, if I am correct. Give me one second while I find it.
Okay. So the reason why Page 1216 is there is because it starts the section on ovarian cancer, which then continues on to Page 1217. And it says -- the last paragraph on Page 1217 says, "Other suggested factors affecting ovarian cancer risk include talc exposure, a history of mumps infection, and alcohol consumption. Talc exposure, which has been related to an excess risk of ovarian cancer in a number of case-control studies, is of interest biologically in that ovarian cancer is thought to arise from the mesothelium that lines the peritoneal cavity."
MR. ROTMAN: Slow it down so she can

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get it.
THE WITNESS: Oh, I'm sorry.
A. "Ovarian cancer may be analogous, therefore, to plural mesothelioma, which has been shown to be caused by asbestos, a chemical similar to talc."
Q. Is that the complete passage that you're looking at?
A. I believe that is why I had highlighted that one, yes.
Q. You'd agree that this version of Blaustein's textbook was published in 1994?
A. Yes, I am aware.
Q. Would you agree that a number of the risk factors that have been identified here, there have been additional studies published on?
A. Yes.
Q. Would you agree that alcohol is a known risk factor these days for ovarian cancer?
A. I don't think that's been borne out to be the case. But with talc, there's continued to be several case controls and meta-analyses which have continued to be consistent with the increased risk of ovarian cancer cited in the studies that were cited here, which I didn't

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actually Xerox. You have the book, so --
Yes, I agree this was 1994, but taken into context of the subsequent studies and literature looking at talc and ovarian cancer, I think it's still relevant.
Q. Have there been a number of updates and changes to the classification of tumors since 1994?
A. Since 1994, sort of semantically. We still have the same subtypes of ovarian cancer. There's been a new categorization. We talked about the Type 1 and Type 2 ovarian cancers.
So not a complete overhaul in categorization; I think just different ways to category the same entities, let's --
Q. Has the --
A. -- put it that way.
Q. Sorry.
Has the understanding of the origin of ovarian tumors evolved significantly since 1994?
A. So this mentions -- we talked about this a little bit earlier -- this does mention that at this time, in 1994, there was thought that ovarian cancer might arise from the mesothelium. So the ovary is covered by a layer

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of mesothelium. That's the outer layer. And so in 1994, that was still, I would say -- this is before my residency, a little before my time -- that that was the most common thought, that that's where the ovarian cancer -- cancers are arising from. Now, since then we've discussed some of the other more recent findings of the etiology.

But, anyway, I just -- I had read this a couple of days ago and, you know, it was -- it was a reference that I think is still relevant because of the -- the subsequent case controls and meta-analyses that were done since then that I think still make it relevant, although, again, I -- we're not -- we're still not absolutely sure where all of these ovarian epithelial tumors are arising from. But we have a little more evidence than we did in 1994.

Q. And in 1994, the first prospective cohort study had not yet been published; correct?

A. I believe that is correct.

Q. So we would be -- these numbers here in -- that are discussed for talc exposure would be, essentially, just the retrospective case controls that had been published up to that point

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or the specific ones --

A. Yeah. You have the reference list of the reference numbers 47, 69, 70, and 182.

Q. Cramer? You said 59?

A. 69.

Q. Harlow, 92.

A. 70.

Q. 70. Hartge.

And 83.

A. And 182.

Q. And Whittemore, 1988.

A. So, yes, that was before. They only looked up until 1988.

Q. Okay.

MR. ROTMAN: Hunter, a good time to take our lunch break? It's been an hour since our last -- since we started.

MS. AHERN: Sure. I'm sure people could use a bio break too.

Q. Are these the only pages that you photocopied from this book -- or in -- sorry. Let me rephrase that.

Have we finished with the photocopy of Exhibit 11 or are there more pages?

A. I think -- I think I Xeroxed this last

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page just because it was a continuation of that. So, yes, I think we're done with the fourth edition.

Sorry. I'm starting to talk fast because I'm excited for lunch.

MS. AHERN: We can take a break for lunch, then.

THE VIDEOGRAPHER: Here ends Media 3. Off the record, 1:05 p.m.

(Lunch recess was taken.)

("Blaustein's Pathology of the Female Genital Tract," Fifth Edition, marked Exhibit 12.)

(Excerpt of Blaustein's Pathology of the Female Genital Tract," Fifth Edition marked Exhibit 13.)

THE VIDEOGRAPHER: Here begins Media No. 4 in today's deposition of Sarah Kane, M.D. Back on the record, 1:45 p.m.

BY MS. AHERN:

Q. Okay. Hi, Dr. Kane.

A. Hello.

Q. I'm looking here at Blaustein's Pathology of the Female Genital Tract, Fifth Edition, which you brought with you here today.

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I marked it as Exhibit 12 to your deposition. You can have it back.

A. Okay.

Q. Thank you. And inside, you brought with you a photocopy of the cover page and also Page 629. I'll hand that back to you. I think there's only one copy. I've marked that as Exhibit 13.

A. Oh, okay.

Q. Here you go.

A. Okay.

MR. TISI: What was the page? I'm sorry.

THE WITNESS: 629. Do you want the textbook back?

Q. Whichever one you'd rather actually pass back to me. Thank you.

Can you tell us, on Page 629, what information you thought was relevant to your review of the talc issue?

A. Yes. I believe this is under "Foreign Body." So this is diseases of the fallopian tube. So under "Foreign Body" -- hold on one second. Okay. It says, "Foreign material may be introduced into the tube in the course of

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gynecologic investigation, especially hysteroscopic -- I can't say the word, hysterosalpingo -- anyway, HPG, lubricant jelly, mineral oil and starch and talc powder may cause a lipoid or granulomatous salpingitis. An intense phagocytic reaction to introduce lipid material causes" --

THE COURT REPORTER: Excuse me.

A. Sorry. I think that's basically the -- that is the end.

No. At the very end of the page, it says, "Talc may cause mucosal or serosal granulomas. Examination of all granulomas or foreign body reactions under polarized light is useful in the recognition of these processes. Other disease processes in the tube such as leprosy or amyloidosis are so infrequent that they are of little clinical or pathologic significance."

Q. How does that information inform your opinions today?

A. So it's just another -- again, similar to the other things that we reviewed in the other edition, just another piece of evidence that talc causes mucosal and serosal granulomas, and they're talking about the fallopian tube in this

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chapter.

MR. KLATT: Can I interrupt?

(Discussion off the record.)

MR. LOCKE: I'm on right now. Thanks, Mike.

BY MS. AHERN:

Q. And, Doctor, did you review any other sections of Exhibit 12, Blaustein, Fifth Edition?

A. I believe I did. I think in this edition, from what I recall, that was the -- the reference was in the fallopian tube.

Q. Is that what we just discussed on Page 629?

A. Yes. 629 was where talc was discussed in the fallopian tube.

Q. Did you see any other information in any of the Blaustein texts that we reviewed today that suggests that foreign body granulomas caused by talc have been associated with the development of ovarian cancer?

A. Well, we saw mention of the epidemiologic studies in the fourth edition that we reviewed.

Q. So other than the epidemiology, is there any reference to pathology studies or

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experimental studies or animal studies linking talc foreign-body responses to development of cancer?

A. From what I can recall in those textbooks, I don't think they went into any more detail than what I've read for you.

Q. Okay. What else did you bring with you today? Anything that we haven't covered other than the boxes behind me?

A. Correct. I don't think so. Mr. Rotman brought a copy of my report, but that is all. This -- let me look.

All of these have been marked already. Yeah.

Q. All right. Doctor, you've got a copy, but I'm going to hand you another one. I've marked as Exhibit 14 a copy of your expert report dated November 15, 2018.

(Rule 26 Expert Report of Sarah E. Kane, M.D. marked Exhibit 14.)

Q. Can you review Exhibit 14 and tell us if this is indeed your expert report dated November 15, 2018?

A. Yes. This appears to be my report.

Q. And you brought with you earlier an

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updated copy of your CV; correct?

A. Yes, I did.

Q. Which we marked Exhibit 2.

(Document entitled "References Cited and Other Material and Data Considered" marked Exhibit 15.)

BY MS. AHERN:

Q. And Exhibit B to your report was entitled "References Cited and Other Material and Data Considered." I've marked that as Exhibit 15 to your deposition.

A. Okay.

Q. Okay. And Exhibit 15 isn't paginated but consists of 11 pages. The first ten pages of materials consist of 186 items identified by the caption on the top of Page 1 as "Literature"; is that correct?

A. I'm sorry. Are you talking about the "References Cited and Other Material and Data Considered," Exhibit 15?

Q. Yes.

A. Yes. There is a list of 186 literature references.

Q. And the materials listed on Page 11 are identified by a caption as "Other Sources" and

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include an additional 17 items; is that correct?
A. Yes.
Q. Okay. So did you prepare Exhibit 15?
A. Yes. I did.
Q. Did you type this out yourself?
A. I did. Yes.
Q. Okay. And how did you go about pulling this together?
A. I'm -- in what way?
Q. Did you keep a running list of the citations as you went and then pull this all together at the end of your report?
A. Yes. So what happened is this was my first medical expert witness report I have written. And you'll notice that -- let's see, all of the -- oh, I'm sorry. This doesn't include the January 4th list; right?
Q. We'll get there.
A. Okay. So that's what I kind of want to explain. What happened is, the reason why you had a January 4th list, is because I wrote this -- the accepted form for published literature is listing literature that you've actually cited within the body of your report, and so it was my misunderstanding. I was not

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aware at first that you guys were going to want a list of everything that I had reviewed.
So what I tried to do is this, I think, was turned in at the same time, so Exhibit 15 was turned in at the same time as Exhibit 14, and it has the literature that was cited within the body of the report.
And then when I realized I needed to get a list together of everything, as complete a list of everything that I thought I reviewed, I put together the January 4th list, which was -- I had to sort of recreate -- and I kept almost all of those -- all of this literature in different files.
I had to do a little bit of recreation because, as I mentioned before, I lost a couple of hard drives during this whole process, which was not fun. But thankfully, I was -- I had backed up a lot of it.
So I tried to be as complete as possible. It is possible that there are a few things I reviewed that did not make the list, which I think I realized on the list that you got yesterday there might have been a couple that I had reviewed before, but most of that literature

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that you -- the list that you got yesterday is stuff that I had reviewed, I believe. I have to look at it.
But my point is that list that you got yesterday was varied, and -- when I looked at it, and it was just an effort to be as complete as possible.
Q. Okay. And just looking -- we'll get there, but just looking at Exhibit 15, which -- the first ten pages, which are the references?
A. Mm-hmm.
Q. So do you define the references as the specific sources that you cited within the body of your report?
A. These are sources that I cited within the body of my report.
Q. And are these the sources that you rely on to support the opinions expressed in your report?
A. So these are some of the references that I used. Again, I also had reviewed the subsequent -- the literature and the other data in the subsequent lists. So I would not say this is all-encompassing, but ultimately, with all the lists you have now, I'm hoping that that is

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encompassing of at least all of the stuff that I considered. I wouldn't necessarily say "rely on," but at least everything that I considered.
Q. Okay. And that was -- my next question was: Do you differentiate between the sources cited here as references and those that you just considered but weren't included as references?
A. Not necessarily. These are the ones that ended up getting cited in the report. Now, there were different drafts, which at one point some of the other ones were cited, and there was a little bit of changing it around, which there's a couple -- I think there are a couple of typographical-type errors in a couple of the references because of that.
But essentially, there isn't that much of a difference, I would say, except to say that this is the literature that I ended up specifically citing.
But all of the literature that I looked at, I considered.
Q. Would you say that all of the literature that you looked at, which would include your other sources here on Exhibit 15, your January 4, 2018, reference list, and the

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ones served yesterday, January 24th, would you say that you relied on all of those materials?
A. No. Well, I at least reviewed those. I would say that I considered them. I wouldn't necessarily say that I relied upon them.
Q. And when you consider material, what does that mean to you?
A. Well, you know, when I'm -- you can look at my methodology, how I tried to cast as wide a net as possible with the information that I gathered in the information stage. So I wanted to have as much data, as many literature references, expert reports, whatever I could kind of get my hands on that might be relevant to my general causation report.
And then I'm reading through those, and that's actually when I started my draft of the report. It really started as sort of notes that I took as I read the different literature references, and I sort of built out from there.
Does that answer your question?
Q. I think probably so.
Did you collect -- did you identify all of the materials in Exhibit 15 yourself, or were some of these provided to you by the plaintiffs'

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counsel?
A. The vast majority of them, I found through my own literature search. Some of them may have been supplied by the plaintiffs' attorneys. A lot of those overlapped with what I had already found; the exception, of course, being documents on the other sources that I would not have had access to on my own.
So I had asked for, and in forming my opinion, my general causation opinion, I had asked for defense expert reports so I could get a sense of what the defense experts' opinions were, just to get, you know, the other -- just to get more information.
So that's -- so those were definitely given to me by plaintiffs' attorneys.
Q. Do you remember, timewise, did you review the defense expert reports and the materials in the other sources earlier on to get a sense of the issues in the litigation and then do your literature search, or the other way around? What was the timing?
A. I don't remember exactly. I don't believe I read the -- I'm trying to think timing.
I think what I did is -- from what I

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remember, I did my own literature search, read as much as possible, started taking my own notes. And then thought, as I was sort of forming my opinion, thought, you know, it would be nice to know what the defense is saying. And, of course, I think at that point is when I asked, but I don't remember specific timing.
Q. And did you specifically -- did you ask for specific defense reports or specific defense reports related to particular expertise?
A. If I recall -- I'm looking at this list -- I believe the first request was a more general request.
Q. When you say "more general," do you mean for --
A. Meaning --
Q. -- for defense?
A. -- I didn't ask for specific names of people.
Q. Ah.
A. I think at this point, I wasn't necessarily aware of who would have been defense experts. And so I don't remember exactly, but my inclination is that I had asked for a more general sort of representation.

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Q. And can you identify on here which of the other sources are from defense experts?
A. Yes. I'll try my best.
The Michael Ober expert report was provided by plaintiffs' counsel. The deposition of Alice Blount was also provided by plaintiffs' counsel. Both of the Chodosh, his report and his trial testimony, was provided by plaintiffs' counsel. Samuel Cohen was provided by plaintiffs' counsel.
And also -- also, let's see, the Cramer, I wouldn't have access to the Cramer reports on the Byrd and Jacqueline Fox. The expert report of Michael Crowley was given to me. That, obviously, is a plaintiffs' report that was within a day or two of turning in my report. That was very late in the process.
John Godleski, I might have asked for by name. Of course, he's a plaintiffs' expert. His, I may have asked for by name because of the Cramer papers.
Q. Did you say Cramer was a plaintiff or defense expert?
A. Cramer, I believe, was a plaintiff.
Q. I wasn't sure. You named him after the defense experts. I'm sorry. I'm just going

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through the list.
MR. ROTMAN: The list is alphabetical, so she's going down the list.
BY MS. AHERN:
Q. Yeah. My question was: Which ones are the defense experts?
A. I'm sorry.
Q. If you're done, you're done. Are there any other defense experts.
A. Well, the John Hopkins and Julie Pier, those exhibits and depositions I got from plaintiffs' counsel.
I believe that is it, looking at the list of defense reports.
Q. Did you want to know what the defense experts had to say about epidemiology?
A. I wanted -- yeah. I wanted as much evidence as I could get, so --
Q. Were you aware that the defendants had designated epidemiologists in the litigation who had given reports and testimony?
A. I don't know if I was aware specifically of that.
Q. Were you aware that the defense had designated a number of gynecologic pathologists

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who had given reports and testimony as well?
A. Again, I don't know if I was specifically aware of that. No.
Q. Would you have, as a pathologist doing an expert report on this litigation, would you have been interested to know what the defense pathologists had said?
A. Well, I will take any data that I can get to try to see if it's relevant. I mean, so I had asked for defense reports, and that's what I got.
Q. These reports, these other sources, the 17 items here were in response to your request, but they were chosen by the plaintiffs' counsel?
MR. ROTMAN: Objection.
A. I'm not sure how they were chosen or how -- why -- all I know is that I asked for reports, and this is what I received.
Q. And you specifically asked for defense reports; right?
A. I did.
Q. And you got Michael Beer, who is an oncologist; Lewis Chodosh, a cancer biologist; and Sam Cohen, a toxicologist; correct?
A. That would appear, from the list, the

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ones that I received. Yes.
Q. Is there anyone on this list that's -- that specifically addresses gynecologic pathology?
A. I think it's been a long time since I read those reports, but I do remember some of those reports speaking to -- your question was on top. I'm just making sure.
Q. Sure.
A. Some -- so the gyn onc report definitely went into some gynecologic pathology. Gyn oncs are generally knowledgeable about gyn pathology because we work pretty closely with them. We often show our gyn pathology, for example, at multiconferences, multidisciplinary conferences.
So I vaguely remember a gyn onc one going over some gyn path stuff, but my memory is vague because I have not read these in probably over a year. I don't know exactly.
Q. Would you be interested in what the epidemiologists that had served reports and given testimony in the litigation the last five years, what they've said?
MR. ROTMAN: Objection.

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A. Again, I'll take whatever information or data, you know, I can get that might be relevant.
Q. And do you consider expert litigation reports to be data?
A. Yes. I think it's data.
Q. Okay. Is it the kind of data you rely on in your everyday practice as a pathologist?
A. I sort of view they're opinion reports. They're opinion, general causation opinions, and a couple of these are -- I can't remember. All of these were general, I believe, from the defense.
So they're professional opinion data, and I would say that's similar to having a consultation with a colleague or a peer. I mean, you know, in my day-to-day practice, I'm certainly asking opinions of colleagues and different specialties or my own specialty, even. Those are professional judgments, professional opinions, looking at their knowledge of the literature or data.
So I think it's a good analogy; looking at general causation, professional opinions, is similar to kind of getting a colleague's opinion.

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Q. But this is the first time you've relied on litigation reports to inform your own opinions; correct?
A. Well, again, I don't know if I would use the word "rely." I certainly considered them, you know. But, again, I think it's very similar to asking a colleague in my daily practice for an opinion on something.
Q. And, Doctor, looking at 186 references that are cited in Exhibit 15.
Did you review each one of these carefully and thoroughly?
A. I reviewed each one of them, some of them probably more thoroughly than others, depending on what I was looking for; but yes, I reviewed all of them.
Q. And do you know whether or not the boxes, the four boxes that are sitting behind me, do those include these 186 references on Exhibit 15?
MR. TISI: Let me see if I can help you out.
MS. AHERN: Sure. Go ahead.
MR. TISI: My understanding is they do.
MS. AHERN: That's the 186?

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MR. TISI: That would be the references in the report. It would not be, to my -- I haven't cracked the boxes, so I can only assume from past prologue that the information considered is not in those boxes. They may be, but the information relied on that is cited in the report are.
MS. AHERN: Okay. So other sources here that are not cited specifically, well, they may be --
MR. TISI: I don't know, for example -- well, maybe we can open them up. But I don't know, for example, if the expert reports and depositions are in the -- in there. If they're cited, then they're probably in there. If they're not cited --
THE WITNESS: I'm not sure because -- I'm not sure I cited these in my report because they weren't necessarily reliance. It was more data.
But I thought at the time that I should list what -- because these aren't publicly -- I don't believe any of these are publicly available, what is on this list, so I felt like I should list them.

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But I don't believe I -- well, I might have referenced the Longo.
BY MS. AHERN:
Q. Page 5. I think if you look at Page 5 of your report, you reference Dr. Blount --
A. Yes.
Q. -- Dr. Crowley, Longo, Rigler, Hopkins --
A. Yes.
Q. -- Pier?
A. Yes. Looking back at the list, you're absolutely correct. I did.
Q. Do you think, as you sit here, that those are --
MR. TISI: I can look at them if it makes your life easier. I'm happy to do it.
But I do think -- Mike is back there looking. I'm thinking that those are the actual, relied-on referenced materials, not the materials considered, which was a separate list.
MS. AHERN: That's the January 4th, and we're going to get to that one.
MR. TISI: No. it's in the back of the report. Maybe I'm wrong.
MS. AHERN: There are other sources,

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but she has apparently relied on them --
MR. TISI: That's fine.
MS. AHERN: -- to some extent in performing reviews about fragrances and asbestos.
BY MS. AHERN:
Q. Is that right, Doctor?
A. Dr. Crowley's report and Dr. Longo's report, yes. I --
Q. And what about Dr. Hopkins and Pier?
A. Yes. I don't believe I read their entire depositions. I know I had seen the exhibits from the depositions, and I think part -- I listed it here, so I must have at some point.
MS. AHERN: Okay. So let's put 15 over here, and let's move on to the next one.
(Document entitled "Additional Material Considered" marked Exhibit 16.)
BY MS. AHERN:
Q. Okay. Doctor, I'm handing you what's been marked as Exhibit 16 to your deposition.
Can you take a look at Exhibit 16 and tell us what that is?
A. Yes. So this is a combination. So once I realized that I needed to give you all a

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list of -- as complete a list as I could -- I'm not going to say this is a complete list -- and, of course, you have another list that you just got, but I tried to be as complete as I could in recreating the literature and other reports that I had considered.

So these are ones that, to my recollection, I didn't specifically cite or were not available -- I mean, obviously, I have some of the plaintiffs' expert reports that weren't available to me until after I had written and submitted my report. So some of these were available to me only after -- and the Health Canada came out after my report.

So these are a combination of things I reviewed subsequent to November 15th and stuff that I had reviewed prior to that but had not specifically cited and recreated the list.

Q. Okay. And just for the record, this is -- Exhibit 16 is a four-page document. It's not paginated, but it has 96 items identified as "Additional Materials Considered," so -- served on January 4, 2018.

Can you identify, as you look through these items on Exhibit 16, which of those you reviewed

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prior to the submission of your report and which ones you reviewed after?

A. I can do the best that I can. My memory might be a little -- and I have to jog my memory a little bit on some of them.

Clearly, the expert reports that were dated -- the plaintiff expert reports that were dated after my report, I had not seen --

Q. Mm-hmm.

A. -- prior.

And, again, the Health Canada came out afterwards, so that was not available when I submitted my report. The majority of the rest of the literature, I had read prior to submitting my report.

Q. Okay. Had you seen any draft reports from any of the other experts designated by the plaintiffs in this litigation?

A. Not before my report. I didn't see any drafts. I only saw the final reports after my report was submitted.

Q. Okay. Did you have an opportunity to talk with any of the other experts that were designated by plaintiffs prior to your report being submitted?

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A. No.

Q. And are there some materials on Exhibit 16 that were provided to you or identified for you by the plaintiffs other than -- and I'm not talking about the litigation materials, but the articles?

A. Again, there might have been some that overlapped with what I had already found. I'm looking.

I believe the April 2014 FDA letter may -- although that might have been available on the internet. I might have come across that on my own first.

No. I believe the vast majority of this stuff was stuff that I -- other than those reports was stuff that I had independently already found. That's the only one that is ringing a bell as a possibility, but I also seem to remember finding it on the internet.

Q. Okay. And are any of these materials, materials that you explicitly rely on or, excuse me, are any of the materials on Exhibit 16 materials that you rely on to support your opinions?

A. Again, it's all data that I considered.

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I didn't specifically cite them, but there's certainly pieces of information that helped me come to my conclusion.

Q. And you prepared Exhibit 16, didn't you?

A. Yes.

Q. And do you remember when you prepared it?

A. Very shortly before you received it. So it would have been -- you received it January 4th?

Q. Mm-hmm.

A. I think I -- it was only -- I don't remember exactly, but it wasn't very long before that that I put it all together, after recreating -- trying to recreate as best I could the list of literature that I had reviewed.

Q. And did you carefully and completely review all of the information in Exhibit 16?

A. Again, I reviewed all of it. Some of it was more relevant than others, likely, so -- but I reviewed all of them.

Q. Okay. Obviously, anything that you received after your report is information you would not have relied on to form your opinions in

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this case; correct?
A. No. It's more information for my -- my opinion hasn't changed since I wrote my report. In fact, I know we've talked about Health Canada a little bit, but that was pretty interesting to see that report because their methodology was very similar to mine, and they did a Bradford Hill analysis, and they looked at a lot of the same literature and came to the same conclusion.
So that definitely was supportive evidence, I think -- not I think; it is -- of my opinion.
Q. And, Doctor, I only have one copy of this. It's "Additional Materials to Sarah Kane" that were served last night or yesterday afternoon, January 24th.
(Document entitled "Additional Materials to Dr. Sarah Kane" marked Exhibit 17.)
BY MS. AHERN:
Q. First of all, can you take a look at that?
Have you seen it before?
A. Yes. Yes. I have.
Q. Did you prepare that?
A. I did. I had listed -- there are a

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couple of papers that I realize I had read previously and didn't -- I can tell you Purdie, 1995, Keskin, 2009, I definitely reviewed while preparing my report, and somehow those got off the list.
The other ones, Taher wasn't available. I'm trying to remember Gordon, if I had seen that. If I had seen that before I submitted a report, it was very late. It might have been after.
The IARC heavy metals, I believe I actually cited that in my reference list, but I was trying to be -- it was one of these last-minute, trying to be as complete as possible, so that actually might be a repeat.
The website, I had reviewed prior to turning in my report. And the Longo supplemental report, obviously, wasn't available until January. Same with the depositions. Those weren't available until after they were done.
The Kurman defense report, I asked for recently when I realized that Kurman was a listed -- a named expert witness, which is also why I went through my copies of my old textbooks and my partner's old textbooks. So that, I asked for specifically.

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I think that covers most of them.
Q. What about the EFSA guidance on the use of weight of evidence?
A. Oh, yeah. That, I think, I reviewed after I had submitted my report.
Q. Did that form part of the basis of your opinions or your methodology?
A. It was more of a -- it basically shows that the methodology that I used is very similar to evidence-based medicine that we would use on a daily basis. It kind of went through weight of evidence, and it was sort of helpful to see the similarity of the methodology that I used coming to my conclusion.
Q. Was the methodology you used for preparing your opinions in this case and your report in this case taken directly from the EFSA guidance?
A. No. I think I just -- I saw this EFSA guidance after writing my report.
Q. Did you use any other sort of published methodology on weight of the evidence when you prepared your opinions?
A. I used what we have been trained to use. I mean, it's evidence. It's an

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evidence-based medicine model of methodology and coming to conclusions. So it's -- I tried to do as thorough as possible description of my methodology, which we can refer to in my report if you'd like.
Q. What about the J&J Science Day presentation?
A. That --
MR. ROTMAN: Objection. Is there a question?
MS. AHERN: I'm about to get there if you'd let me finish my question.
MR. ROTMAN: I thought you were. Sorry.
MS. AHERN: You might just hold off.
BY MS. AHERN:
Q. What about the J&J Science Day presentation? Is that something that you reviewed?
A. I reviewed that very quickly, and I only received that maybe a week ago. It was very recently.
Q. Did you request that information?
A. I think, from what I remember, it was part of asking for more sort of defense side of

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the story; what, you know, your experts might have been saying; what kind of -- you know, I was trying to figure out how somebody who had looked at the same body of evidence that I did can come to a different conclusion, so it was part of sort of that request.

I think I probably got it after I requested Kurman's defense report from a prior litigation, if memory serves me correctly.

Q. You would agree that a very large part, not just volume, but a very large part of your report and your opinions in this case are related to the observational epidemiology on talc and ovarian cancer; is that correct?

A. Well, I think that epidemiology literature is extremely compelling. You have 30 case-control studies over different periods of time in different populations that have come to the same -- same ballpark relative risk, I would say, 1.3 to 1.4.

Now, not all of those have been statistically significant, but some of those studies were smaller studies, and so that tends to decrease the power of the study and your confidence intervals will be wider.

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But I thought the epi data was really compelling. And often in causation, the epi data sort of leads the way in paving a path to figuring out causation.

A perfect example is tobacco. You know, the Surgeon General issued his report in the 1960s about tobacco before they had any mechanism for tobacco causing -- so that was a perfect example of the epi data leading to causation.

So it's true, a lot of the studies looking at talcum powder products and ovarian cancer are epidemiology studies, but they're extremely informative in that they are very consistent in their findings. And, again, different authors, different populations, different countries.

And there's also the cohort. So I went through the cohort studies. The cohort studies, some of them showed an association with serous invasive carcinoma, but the cohort studies didn't tend to find, other than that, a statistically significant increased risk, although some of them did find increased risk.

But we can talk about cohort studies versus case-control studies if you want, but I think the difficulty with cohort studies is ovarian cancer

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is such a rare disease, and you're sort of, you know, rolling the dice when you enroll patients as to whether or not they're going to end up with a disease at the end that you want to study.

So you're sort of -- and these cohorts are also designed for multiple endpoints and multiple diseases. They weren't just looking, most of them -- I believe the sister -- well, the sister study -- anyway, we can pull it out if I have to, but my point is the cohort studies are designed for multiple different things, especially the Nurses' Health Study.

And so it's a difficult type of study to design with a very rare disease. And I think that's where the case-control studies are important because you can start with the disease and work backwards, and so you can have an easier time getting cases.

Q. Did you find it interesting or odd that you were provided with a number of defense expert reports, but not a single one of them related to the epidemiology specifically from an epidemiologist?

A. Well, you know, again, I don't pretend to know why I was sent what I was sent. I just

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know that I asked for reports, and I got what I got. So I have no idea what the process was in deciding what I received; if there was even a decision. For all I know, it's just what they had readily available.

Sorry. What is the question?

Q. Well, let me ask another question.

MR. ROTMAN: Let her finish the answer because you can read -- she can go back and read from the realtime what the question was and see if she's done.

A. So I guess I don't know if there was thinking -- what the thinking was or if there was any. But also I can say that the epi data -- I knew that by that point that the epi data was consistent by the time I -- I think that was the first literature that I was looking at, and so I knew that it was consistent.

So it's -- anyway, I don't really -- I don't know is the answer, the short answer.

The long answer, the short answer is I don't know why I got what I did. I just did.

Q. Okay. And you've seen the designations in this case from November of 2017 in which you were listed formally and publicly as an expert

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for the MDL? Have you seen that document?
A. I'm not sure that I have, actually.
Q. Were you aware that in November of 2017, you were listed on a court document as an expert for the plaintiffs in the MDL litigation?
MR. ROTMAN: Objection.
A. I don't know the timing or I don't think I saw the document, so I...
("The Plaintiffs' Steering Committee's Initial Designation and Disclosure of Non-case Specific Expert Witnesses" marked Exhibit 18.)
BY MS. AHERN:
Q. Okay. I'm marking Exhibit 18 to your deposition. Do you see this document, Exhibit 18, is entitled "Plaintiff Steering Committee's Initial Designation and Disclosure of Non-case Specific Expert Witnesses"?
A. Okay.
Q. And if you turn to -- first of all, let's see. Unfortunately, I can't find the date on that, and I apologize.
MR. TISI: It's January, if I'm not mistaken. I think it was mid-January of 2017.
MS. AHERN: Is that what it is?

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MR. TISI: Yeah. And, Counsel, since I was involved in this process, if you don't mind if I place an objection here.
MS. AHERN: Sure.
MR. TISI: As you may not know, during the status conference where this was ordered -- I don't have the transcript in front of me -- it was intended to be an interim -- I don't know what the questions are going to be, but it was intended to be an interim disclosure to help guide the legal process for identifying issues that would be involved in Judge Wolfson looking at the science.
It was never -- I don't know -- again, not knowing what your questions are, I don't even think it would be intended to be used as an expert -- as an exhibit in a deposition.
But, you know, whatever your questions are, we would like to reserve that because --
MS. AHERN: Sure.
MR. TISI: -- this was intended to be a -- more of an informative document than anything else.
MS. AHERN: Okay. Your objection is noted.

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MR. TISI: That's fine.
MS. AHERN: Absolutely.
I have the date as November 6, 2017.
MR. TISI: You are exactly -- well, it is what it is.
MS. AHERN: Okay. Either way.
BY MS. AHERN:
Q. Okay. Doctor, if you turn to -- if you turn to Page 8, the bottom of Page 8, do you see your name?
A. Yes.
Q. Okay. And did you -- go ahead and review the text here associated with your name and designation.
(Witness complies.)
Q. Just let me know when you're finished.
A. I'm finished reading my blurb. I'm just looking...
Q. Sure.
A. Okay.
Q. Were you aware in November of 2017 that you had been publicly disclosed as an expert on behalf of plaintiffs in the MDL?
MR. TISI: Okay. That's -- and you do kind of need to know the context in which this

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was done.
MS. AHERN: I'm just asking if she was aware she was publicly -- she was already retained at that point.
MR. TISI: She was retained, but there was no -- the judge was very clear when she ordered that this be done. She understood that this was not a disclosure of experts.
So when you ask the question "You understand you were being identified as an expert at that time," she would have no way of knowing that because we didn't know it.
MR. KLATT: Chris, you've got to limit your objection.
MR. TISI: No. But it's unfair because --
MR. KLATT: You're coaching the witness. You're telling her the whole story.
MR. TISI: It's a true story. Why don't we ask her to leave, and we'll put it on the record. I have no problem with that.
MR. KLATT: All right.
MR. TISI: We can ask her to leave, and we can put it on the record.
MR. KLATT: Let's do that.

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MR. ROTMAN: Go get a cookie.
MS. AHERN: Sorry, doctor.
(Witness exited)
MS. AHERN: My questions on this are fairly limited to the time period that she was retained, time period she was intending to be an expert, that sort of thing --
MR. TISI: Yeah.
MS. AHERN: -- and the subject matter that she is being designated for.
MR. TISI: Yeah. But, you see, the issue in the case -- and the reason why this was a tricky issue for the judge and -- well, I won't speak for the judge, but for us when we disclosed this was because we didn't know -- we didn't have expert reports. We didn't even have opinions yet.
So this was being done in a way that said, "Okay, Judge, she wants to know, A, are there new and different witnesses that were going to be designated that were different than what was designated in the state court?"
MS. AHERN: I do recall this, yes.
MR. TISI: The second issue, she was very clear that she understood that there was a

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lot of discovery that needed to be done, documents to be reviewed, science that was going to come out. So she was pretty clear that this was more informative than anything else.
And so when you ask her a question about -- when you ask her questions, "You know when this document was disclosed when you were identified as an expert," you know, it implies that she had agreed to be -- you know, what her opinions actually were at that time.
She -- I can tell you that these reports were done over a period of time. So it's misleading, and it really is an unfair thing to do to a witness because this was a court request having nothing to do with her opinions or her expert report.
MS. AHERN: Okay.
MR. TISI: Do you understand where I'm coming from?
MS. AHERN: I understand where you're coming from.
Here is my question to you: Did Dr. -- was Dr. Kane not aware that you were going to designate her or that you had at least publicly disclosed her to the Court?

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MR. TISI: She was probably not, I mean, what she was aware of when she had been retained.
MS. AHERN: Did she agree to be disclosed as an expert?
MR. TISI: She agreed to be retained. She was disclosed as an expert when she reached her conclusions in the case.
And so what the Court was requiring us to do was to give us a broad brush, and she was very clear. I remember standing in court, and she said, "Look, some of these may fall off your list. Some of these may -- we may have people that might be added, but I want a snapshot in time as to what I'm dealing with in terms of" --
MR. KLATT: We don't need to waste time on the record on this.
MR. TISI: We can go off the record if you want. I just don't want to be -- use this as an unfair -- you know, none of your questions have been unfair up until now.
But to take this document and to suggest in some fashion -- and I don't know what you're going to do with it. Maybe we just need to wait and see.

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But I think this is -- I don't think anyone ever intended that this document would be used as an exhibit in a deposition of one of these witnesses. I don't think the court intended that to be the case, just like she -- when she ordered the Tardek report -- informational only.
MR. KLATT: Are we off the record? We're just going on here. Let's go off the record.
MR. TISI: Yeah.
THE VIDEOGRAPHER: Off the record, 2:38 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Back on the record, 2:42 p.m.
(Witness returns)
BY MS. AHERN:
Q. Okay. Doctor, I've just shown you a copy of some early designations that were submitted in the talc MDL, and you saw your name listed as one of the people who was being considered as an expert; correct?
A. My name is in this document. Yes.
Q. Okay. Is there any -- do you have any

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issues with the description of the testimony that you were going to offer to give?
A. I believe that to be accurate.
Q. Okay. And you had been working on your report at this point since May of 2017; correct?
A. I started in May. "Writing the report" is a very loose description. What I was -- what I started, as I mentioned before, was I started to review literature. I sort of took notes. So I sort of counted that as writing. So I started that process in May.
Q. Okay. And the only thing I was going to ask you about in this report is, as you look through it, do you note that there are a number of professional epidemiologists that have been listed in this report on behalf of plaintiffs?
A. I'd have to go through the list. I actually, even though I did have access to several final reports, after I had submitted my report, I don't remember who was what specialty, what field, for the majority of them.
Q. Well, how about this question: Of the experts -- are you aware of which experts have submitted reports on behalf of the plaintiffs?
A. I would need to look at the list that I

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reviewed, which I think is all of the ones that were submitted, and compare it to this list.
I mean, I know Jack Siemiatycki is an epidemiologist, off the top of my head. Dr. Singh, I believe, is an epidemiologist.
But without going through the list and sort of jogging my memory as to the reports, I skimmed a lot of these reports.
Q. Okay. And I guess the point is: Are you aware, as we sit here today, that the plaintiffs have designated a number of epidemiologists in this MDL litigation who have given reports and/or testimony at this point on the topic of epidemiology, talc and ovarian cancer?
A. I am aware that they have epidemiologists that have submitted reports for this MDL.
Q. Okay. And specifically, if you can think back to your initial contact with plaintiffs' counsel when you were asked to get involved in the litigation, what specifically were you asked to do, or what was your understanding of what your role would be?
A. Yeah. My understanding was they had

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asked me if I would be willing to do an extensive review of the literature and decide what my opinion would be on talcum powder products causing ovarian cancer.
Q. Did you ask them or discuss with them what your role would be in terms of your specific area of expertise in anatomic pathology?
A. I did not specifically talk to them about that because I know that I'm a gynecologic pathologist, so I thought that would be my area where I weigh in on my opinion.
Q. And where in your report specifically do you address your expertise in gynecologic pathology, anatomic pathology?
A. I list it in the beginning of my report, I think. I talk about -- I talk about my background.
Is that what you mean?
Q. I mean more in terms of the opinions that you're giving being informed by your expertise in anatomic pathology.
A. Well, again, I'm an expert in gynecologic pathology, and the question is about a causation of ovarian cancer, so certainly that falls into my area of expertise.

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Q. And do you specifically address in terms of anatomic pathology or ovarian cancer pathogenesis the question of talc and ovarian cancer?
A. I think that goes to the plausibility, the mechanisms, as part of it.
Q. And which particular mechanisms are informed by the discipline of anatomic pathology and gynecologic pathology?
A. Well, I think pathologists, anatomical and clinical pathologists, have training in inflammation and immunology and certainly epidemiology, looking at epidemiologic studies. I think all of it is within the realm of gynecologic pathology.
Q. Did you discuss anywhere specifically in your report the biology of foreign body reactions and granulomas as a part of the biologic plausibility for exposure?
A. Let me refer to my report. I definitely talk about inflammation. I can do a word search for granulomas, if you would like.
Q. Do you talk about inflammation --
MR. ROTMAN: Would you like --
Q. -- in the context of anatomic

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pathology?
MR. ROTMAN: Would you like to do that? Because I can get your report up electronically.
MS. AHERN: I know where she's mentioned granulomas. I already know. I'm just asking her if she knows.
MR. ROTMAN: So she wants to find it quickly.
MS. AHERN: You can give her your computer and let her search.
MR. ROTMAN: Okay. That's what I was asking.
BY MS. AHERN:
Q. Do you cite any publications describing the biology of granulomas?
A. I know some of the literature talks about granulomatous inflammation, discusses granulomatous inflammation.
MR. ROTMAN: If you want to search, do you know how to do it on this computer? Edit, Find, then you can type in a word that you want to search.
MR. KLATT: Is there a question?
A. So I mention it in the animal studies, injecting talc into the pleural spaces causes

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granulomatous response. It looks like those are the two.
And then I cite the Mostafa 1985 paper, "Foreign body granulomas in normal ovaries."
I'm double-checking. It looks like in doing a word search for granuloma, that's what is popping up.
BY MS. AHERN:
Q. Okay. Are there any other portions of your report that directly address ovarian cancer pathogenesis from a pathology standpoint?
MR. ROTMAN: Objection.
A. This might be attorney work product draft stuff.
MR. ROTMAN: Do you want to talk to me outside where I can understand what you're getting at?
THE WITNESS: Sure. Sure.
THE VIDEOGRAPHER: Off the record, 2:50 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Back on the record, 2:54 p.m.
BY MS. AHERN:
Q. Okay. Doctor, I had asked: "Are there

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any other portions of your report that directly address ovarian cancer pathogenesis from a pathology standpoint," and --
A. So my answer is I did the work, but I can't discuss it because of attorney work product issues.
Q. Okay.
MR. ROTMAN: You can -- she can -- you can ask her questions about it.
MS. AHERN: Sure.
MR. ROTMAN: But she's -- as to what is in the report or not in the report, that's the work product piece.
MS. AHERN: That's kind of all the questions.
MR. ROTMAN: Ask her about the science.
MS. AHERN: I'll ask, and you can object.
MR. KLATT: Find out what is in or is not in the report.
MS. AHERN: Let's pick up the foundation here.
BY MS. AHERN:
Q. Doctor, first of all, you said you did the work relating to ovarian cancer pathogenesis

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from a pathology standpoint; correct?
A. Yes.
Q. Was it ever in your report?
MR. ROTMAN: That's part of the work product objection.
MR. KLATT: We've got to establish the facts to know whether there's a basis to assert the objection.
MR. ROTMAN: You can ask the question. But in order to answer the question, you're invading the domain of what is protected under the Federal Rules in terms of the drafting of expert reports.
I will object and instruct her not to answer.
What's in the report, you have. What was in drafts of the report, you're not entitled to.
So that's the problem we have.
MR. KLATT: She's not asking what was in the report. She's asking whether it was or isn't. So we can establish if there's anything to even have a dispute about.
MR. ROTMAN: You can ask her about what is in the report all you want.

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MS. AHERN: Well, she's already said there was a section on ovarian cancer pathogenesis from a pathology standpoint in the report, and it was removed; correct?
MR. TISI: That's not what she testified.
MS. AHERN: Read back.
MR. TISI: Why don't we read what she said because she said the answer is:
"ANSWER: I did the work, but I can't discuss it because of attorney work product."
MS. AHERN: Okay. Okay.
MR. TISI: She never said it was in the report.
MS. AHERN: Thank you.
MR. TISI: Line 48.
BY MS. AHERN:
Q. When you say you "did the work," did you take any notes on any reading that you did on ovarian cancer pathogenesis?
A. So in writing this report, I generally did not take any notes, handwritten notes. It was sort of a living document that I used.
Q. Now, earlier, you referred several times to taking notes as you were going through

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literature.
Are all those notes something that became -- on a single document that ultimately became a report?
A. It was one document that went through numerous, numerous editing on my part and, of course, suggestions from attorneys at different points.
Q. Now, as an anatomic pathologist and as the only pathologist that has been designated by the plaintiffs in this MDL, did you think that it was important to opine on the pathogenesis of ovarian cancer from an anatomic pathology standpoint?
MR. ROTMAN: Objection. For what purpose?
MS. AHERN: I'm asking her.
Q. Can you answer the question?
A. First of all, I wasn't aware I was the only pathologist because I didn't have a list of their named experts.
I did work on -- I'm not sure how much I can really talk about the whole draft process.
MR. ROTMAN: You can't --
Q. So my question was: As an anatomic --

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let me rephrase it.
As a gynecologic pathologist who was asked to opine on ovarian cancer and talc, did you assume that part of your opinions would be to incorporate your expertise in anatomic pathology and gynecologic pathology?
MR. ROTMAN: Wait. Wait. Wait. Wait. Wait.
MS. AHERN: I'm only concerned if she understands the question.
BY MS. AHERN:
Q. Do you understand the question?
MR. ROTMAN: No. You have to let me see if I understand the question to see if I'm going to object to it before she's allowed to answer.
MS. AHERN: Why don't you make an objection, and we'll move on.
MR. TISI: Because he may instruct her not to answer the question.
MS. AHERN: This is not -- this is not a question that should invade your privilege.
MR. TISI: It involves the discussion between counsel and in the drafting of the reports, what would be in, what would be out,

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what she thought, what she didn't think. You're not entitled to any of that.
MR. ROTMAN: So if you can find the question, read the question, and I will object to the question, but you can answer it.
A. Okay. So you want me to reread the question?
MR. ROTMAN: To yourself.
So my question was -- do you see that?
THE WITNESS: Yeah.
A. Well, I feel as if I did that in my final report. I certainly -- the -- my opinions that are in my final report are certainly within the realm of gynecologic pathology.
Q. And can you specifically point to the opinions and the discussions in your report that are within your personal expertise in gynecologic pathology?
A. So, again, review of epidemiology is something that physicians do on a regular basis. We're trained to look at epi data. We're trained to practice evidence-based medicine, which has a very similar, if not identical, methodology.
So -- and we certainly are trained in inflammation, the immune system, talc and

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tissue -- I have a section on talc and tissue -- the epi data.

Not -- I don't think any of this report is outside of my -- I know that none of this is outside of my expertise as a gynecologic pathologist.

Q. Okay. Doctor, were you retained as an expert epidemiologist in this case?

A. I was retained as a gynecologic pathologist.

Q. And you are not an epidemiologist; correct?

A. I'm not a epidemiologist, but we certainly review epidemiology and critique epidemiology studies on a regular basis in our daily practice.

Q. When people ask you what you do for a living, you don't tell them you're an epidemiologist, do you?

A. I often have to explain what a pathologist is, so I spend half the time just trying to describe what a pathologist is, so...

MR. KLATT: Objection. Nonresponsive.

MS. AHERN: Yeah.

MR. ROTMAN: She's not done answering

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your question. She's in the middle of an answer.

A. So my point is I'm unlikely to describe myself as an epidemiologist when I'm trying to describe what a pathologist does, but that's the big picture.

But the real picture is, on a daily basis, we are evaluating epidemiologic data in the literature.

BY MS. AHERN:

Q. When was the last time you did a systematic review of the literature for the purpose of opining on causation?

A. So we review literature --

Q. You. I'm just talking about you.

A. Hold on one second. Let me just review the question. I'm way behind here on my --

Well, I do literature searches all the time and looking -- when I'm looking at cases to figure out causation.

I've been involved in one other legal case, but it is -- this was the first medical-legal general causation report.

But, again, this is all the same methodology that we use in evidence-based medicine and our practice.

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Q. You do a full systematic review of the literature, as that term is defined epidemiologically?

A. We certainly do when we're doing research, when we're writing papers, but we still do literature searches when we're assigning out cases that are relevant to individual patients.

Q. When was the last time you conducted a full systematic review of the literature and a Bradford Hill analysis to opine on causation?

A. So, again, this is not something that's completely foreign to me. The legal aspect of it is new to me, but this methodology is not new to me.

The last time -- I mean, there was a tobacco case that I worked on, but in my daily practice, again, I'm still looking at epidemiology literature all the time.

Q. Well, there is a difference, Doctor, wouldn't you agree, between looking at the epidemiology to inform yourself about a particular issue and doing a systematic review of the literature and a full Bradford Hill analysis to opine on causation? Is there a difference?

A. Well, this was a deep dive, so I'll say

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I was aware of the literature on talcum powder and ovarian cancer before I became involved in this litigation.

I will say, you know, it wasn't until they asked me to form my opinion on this that I did a deep dive on the literature again on this particular issue.

Again, I've certainly done extensive literature reviews before to, you know -- in research and in practice.

Q. But nothing like this?

A. It's very similar.

MR. ROTMAN: Objection.

A. The methodology is very similar to this. It's identical.

Q. Doctor, can you point me to -- take a look at Exhibit 2, your CV.

Can you point me to something in your CV that demonstrates some specialized knowledge or expertise in epidemiology? A course, a class you've taught? A paper that you've published? A case-control study you've been involved in? Anything that would indicate that you have specialized expertise in epidemiology?

A. It's part of our medical training as

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part of evidence-based medicine.
I'm trying to find my CV. I'm not sure I have it in front of me. Maybe it's under here. Well, you're sitting in -- I mean, all of these involved epidemiology research.
MR. ROTMAN: All of what?
A. I'm sorry. All of these research projects start with -- the pathology publications start with looking at the literature of epidemiology.
Q. Which ones are you pointing to -- sorry. Let's look at the peer-reviewed publications.
Is that what you're talking about?
A. Yes. Sorry.
Q. So the first publication is Narasimhan, "Temperature Induced Interstrand Crosslinks in Cisplatin-DNA Adducts Detected by Electrophoresis and UV Spectrophotometer."
That's not an epi study, is it?
A. Some of these were biology. The one that comes to mind when I'm looking at this list is the "Yersinia pestis and the plague." That was a review article. That was around -- that was after the 2001 mailings of the pattern

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substance. And so the literature was very interested in Yersinia pestis at the time, and so I did a review article on that.
Q. Was that a systematic review and a Bradford Hill analysis?
A. The Bradford Hill analysis is part of evidence-based medicine when you're coming to a conclusion. So --
Q. This isn't a case-control study or a prospective cohort study --
MR. ROTMAN: You're not allowing her to finish her answer.
Q. -- or epidemiology study, is it?
A. But my general causation opinion is very similar to a review article on causation. It's a review of the epi data and mechanisms.
Q. Did you do a full review of the epi data and mechanisms on Yersinian plague?
It's kind of a done deal; right? We already know that; isn't that right?
A. Well, you're still looking at -- you're still looking at data. The question is -- the question was at the time: Can Yersinia pestis be a dangerous weapon of destruction or terrorist-type agent?

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So that was sort of more the review on that.
Q. Who is S.M. Rollins?
A. That's my ex-husband.
Q. What is his specialty?
A. He's a microbiologist.
Q. What about Ryan?
A. He is an infectious disease physician.
Q. Okay. What portion of "Yersinia pestis and the plague" did you draft or did you contribute?
A. I drafted the entire -- I was the lead author, and I -- the primary author, and I drafted that report.
Q. Okay. So if we go in there, we're going to find you used statistical methods or analysis in any way to weigh the evidence and conduct a systematic review?
A. It's definitely a review article. Off the top of my head, I don't know if I did a statistical analysis, but...
Q. Would you describe it as more of a narrative review of the literature?
A. A review of the literature. I don't know about the word "narrative," but review.
Q. What about the Grundy paper,

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"Specificity of tRNA-mRNA Interactions in Bacillus substilis tyrS Antitermination"?
Is that an epi study?
A. No.
Q. What about the Rollins paper, "Diagnostic yield of muscle biopsy in patients with clinical evidence of mitochondrial cytopathy"?
Is that an epidemiologic article?
A. No. That's not an epidemiology article, but we --
Q. Sorry?
A. It's getting late in the day.
MR. TISI: Do you need some water?
THE WITNESS: Sure.
A. But it's interesting that it actually did involve electron microscopy. And when we do muscle biopsies for mitochondrial cytopathy, we use electron microscopy anyway, regularly.
MR. KLATT: Objection. Nonresponsive.
Q. And what about the Rollins "Autoimplants and serous borderline tumors of the ovary: A clinicopathologic study of 30 cases and a process to be distinguished from serous adenocarcinoma"?

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Was that a systematic review of the literature, or an epidemiologic study?
A. There's definitely review of literature as part of that study because the question arises with autoimplants, sometimes they're misdiagnosed as invasive serous.
So there is definitely literature review for that study.
Q. This would be described as you have it in the title, this is a clinicopathologic study?
A. Correct.
Q. So you were looking at this as a pathologist; correct?
A. Well, I'm looking at -- I mean, some of these were before I was -- the first couple are before I was an M.D., but all of the subsequent ones I'm looking at as a pathologist.
Q. What about the Chan study, "Clinicopathologic Correlation of Fetal Vessel Thrombosis in Mono- and Dichorionic Twin Placentas"?
Is that an epidemiologic study?
A. That's a clinicopathologic correlation.
Q. And then the publication with Jonathan Hecht, "Endometrial Interepithelial Neoplasia,"

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is that an epidemiology study?
A. That was a review of a new terminology in endometrial precursor lesions. So that was a pathologic -- an anatomic pathology article.
Q. And then you have the one with Haspel, which is "Successful Implementation of a Longitudinal, Integrated Pathology Curriculum During the Third Year of Medical School"?
A. That was a medical-education-type article.
Q. Okay. And do you have any proceedings of meetings, poster presentations, that were from a case-control or a cohort study that you conducted?
A. Let me look. I don't believe these poster presentations were case -- well, I mean, case-control or cohort epi-type studies.
Q. Okay. And, Doctor, to be fair, you don't have a degree in epidemiology; correct?
A. I do not have a degree. But, again, it's -- epidemiology is a very big part of evidence-based medicine and what we practice as M.D.s.
MR. KLATT: Objection. Nonresponsive.
Q. And, Doctor, you understand that there

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are degreed epidemiologists who have been designated on behalf of plaintiffs to look at these issues; correct?
A. I'm aware of that now. I didn't know who their list was before I submitted my report.
Q. You've never published -- as we just looked through here -- an epidemiologic study, a case-control study, or a cohort study?
A. I have not published; but, again, that doesn't -- I mean, it doesn't mean I haven't done them. It's just that --
Q. Have you done them?
A. They haven't been published. Well, again, literature reviews of epidemiology is part of our regular practice.
Q. I'm asking about, like, actual study designs.
Have you conducted a case-control or a cohort study?
A. Not of an epi- --
Q. Okay.
A. -- specific design.
Q. Have you ever taught an epidemiology course?
A. No.

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Q. Do you have any grant funding to conduct epidemiologic observational studies?
A. No.
Q. Have you ever given any lectures or presentations specifically on epidemiology methodologies?
A. That's possible. I'm trying to think. It's been a long time. Medical school through residency, fellowship, not that I can think of off the top of my head.
Q. Okay. And have you ever designed a clinical trial?
A. I have not designed a clinical trial.
Q. Have you designed a case-control study?
A. I have not designed a case-control study.
Q. Have you designed a cohort study?
A. I have not designed a cohort study; but, again, these are -- we can critically evaluate. Just because I haven't designed one doesn't mean I can't critically evaluate case-control studies or cohort studies.
Q. Doctor, you haven't conducted a meta-analysis or a pooled analysis to evaluate potential risk factors for any disease, have you?

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A. No, I haven't.
Q. Are you qualified to conduct a meta-analysis or a pooled analysis?
A. I'm -- I'm sure I could develop one.
Q. As we sit here today, are you qualified to conduct a meta-analysis or a pooled analysis?
A. If it was sort of a joint venture, I'm sure; but, again, that doesn't mean that I can't critically evaluate them, because that's what I do on a daily basis.
Q. Have you authored any paper or conducted a study -- well, have you authored any paper on the methods of causal interpretation?
A. Have I authored a paper on the methods of causal interpretation?
I don't believe I've authored. It would be on my list.
Q. Okay. Doctor, I should have asked you this when it was in front of you: Do you have a copy of that one-page additional materials?
A. Probably. Let's see.
Q. Thank you. Maybe I have. Maybe I have it too.
A. Exhibit 17?
Q. Yes. Yes.

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You received a copy of the Longo supplemental report; correct?
A. I did. Yes.
Q. And it's, what, 404 pages?
A. That's possible. I don't think I looked.
Q. That was my next question: Did you review it?
A. I did review it. I did skim a lot of it because, again, it was additional information that was nice to have, but it was after my report.
And, again, my general causation opinion is not dependent on asbestos being in the product. My general causation opinion is based on whatever is in the bottle. So it was interesting information to have.
Q. So your opinions here, it doesn't matter for your opinions whether or not there's asbestos in talcum powder products; is that your testimony?
A. What I'm saying is my opinion is based on whatever is in the talcum powder product's bottle. Now, it's up to the jury to decide if there's asbestos in it. However, if there is

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asbestos in it, that would certainly add to the plausibility of causation.
Q. If there was not asbestos in talcum powder products and there was not fragrance in talcum powder products and you were just left with the pharmaceutical-grade talc, what would your biologic plausibility argument be?
MR. ROTMAN: Objection.
Q. In other words, what is your mechanism by which pharmaceutical-grade talc would cause ovarian cancer?
MR. ROTMAN: Objection. Are you asking about causation or about biological plausibility?
MS. AHERN: I'm asking --
MR. ROTMAN: You mixed them.
MS. AHERN: -- about her mechanism.
BY MS. AHERN:
Q. What is your mechanism by which pharmaceutical-grade talc would cause ovarian cancer?
A. So there are -- again, most of the studies are dealing with talc powder products. If we were to say that all that was in there is pharmaceutical -- it's completely hypothetical because I don't know what's in there -- I still

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think the mechanisms would be similar where, you know, there's evidence that talc can cause inflammation, and we know that inflammation is a cause of cancer.
And so I -- and there's also, you know, Dr. Cramer talked about anti-MUC-1 antibodies, so there's an immune -- plausible immune mechanism, so I think all of those are still on the table and the hypothetical situation that it's only pharmaceutical-grade talc in that bottle.
But, again, I -- I'm not opining about what is in the bottle; I'm just opining about that -- whatever that product is in that bottle causing ovarian cancer.
Q. Okay. Let's take a look at your expert report again, Exhibit 14, if you will.
Just let me know when you've got it.
A. Yeah.
Q. Okay. Doctor, does Exhibit 14, your November 15, 2018, expert report, contain all of the opinions that you intend to offer as a witness in this matter?
A. I wouldn't box myself in that way. There might be questions that I'm asked here today or in trial that aren't necessarily in my

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report.
Q. Okay. But the opinions that you intend to offer, absent somebody asking you to offer other opinions, are all outlined or contained within Exhibit 14, your report; is that correct?
A. Again, I wouldn't want to say "all." I wouldn't want to limit myself. There's always the possibility that something else will come up, and I even have a thing that additional information may come up.
Q. Okay. As we sit here today, do you understand that this is our opportunity to ask you about the opinions in your report, and we have the day to do it?
Do you understand that?
A. I understand.
Q. Okay. So to the extent that you think you're going to offer additional opinions or different opinions, we need to know that today.
I understand that if something comes up two weeks from now and it's additional information, you might supplement your report.
But as of today, as we sit here today, is this report an accurate reflection of the opinions that you have formed and that you intend

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to offer in this case?
A. I would say it's an accurate reflection of the opinions I have formed with the exception of anything that might be asked that is not in the report; but yes.
Q. All right. All right.
And as we sit here today, is your report complete?
A. Well, it's signed and turned in, so --
Q. Do you, as the expert designated in this case, Sarah Kane, do you consider your report to be complete as we sit here today?
A. Yes.
MR. ROTMAN: Off the record.
(Discussion off the record.)
THE VIDEOGRAPHER: Off the record, 3:24 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Here begins Media No. 5 in today's deposition of Sarah Kane, M.D. Back on the record, 3:39 p.m.
BY MS. AHERN:
Q. Okay. Dr. Kane, we were talking about your report. Just some basic housekeeping first.
We have the four boxes back here which

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probably have within them all the references to your report. Other than those and what you brought with you today, is there anything else related to your work on your report that you have in your possession that you haven't been able to bring with you today?
A. Not that I'm aware of. I've tried to be very complete in my list of what I reviewed. It's possible -- again, it's possible there are a couple of things that might have been left off, but I tried to be as complete as possible.
Q. Okay. And you mentioned earlier you had done some work on the pathogenesis of ovarian cancer.
Did you have any articles or publications that are related to that work that are not referenced in your report?
A. I believe they should be in the list. They should be included in the list that you have.
Q. The one from -- your initial report?
A. Taken all together. Taken all together. So that, probably, is more -- the January 4th one would probably be some of those.
And then I can't remember what's on that one

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that you just got, but if there's a couple on there.
But I would think if they weren't cited in the report, the majority of those should be in the January 4th list.
Q. Okay. And those would pertain to the various histologic categorizations of ovarian cancer; what is known about etiology.
Is that kind of the gist of the information that you researched?
A. Yes. Yes. That was certainly part of it.
Q. And were there other parts to that?
THE WITNESS: Is that -- I don't know if --
MR. ROTMAN: Yeah. You can say what work you did.
A. There was -- so a good bit of it was sort of background information on the pathologic diagnosis of ovarian cancer and different, as you said, different subtypes.
There was -- I'm trying to remember -- it was so long ago -- what some of the -- I believe there was a little bit more on inflammation, but I can't say for sure.

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BY MS. AHERN:
Q. And would that have been just related to ovarian cancer pathogenesis?
A. Yes. Yes.
Q. And you think that all of the publications that you found, identified, reviewed in relation to that work are identified in one of the lists or across several lists?
A. I'm hoping that across all of the lists, that encompasses the vast majority, if not all. But let's just keep it at vast majority.
And, of course, you know, I'm a gynecologic pathologist, so I read tons of other stuff that, you know, is just my background knowledge that I'm not going to put on these lists. So I can't say it's all-inclusive; but, again, I tried.
Q. Understood. Understood.
And you've now seen at least one report from Dr. Robert Kurman; correct?
A. That's correct. That was an individual causation report, though. So...
Q. And he had a very large background section on ovarian cancer pathogenesis; correct?
A. To be honest with you, I sort of skimmed it, but I do remember seeing a section on

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that. Yes.
Q. Okay. Did you skim the section that was case-specific?
A. No. Mostly the background since I already know that stuff.
Q. Okay. And is the stuff that was in his background section similar to the research that you did?
A. I would say yes. If I am remembering accurately, it was similar. I wouldn't say identical, but similar.
Q. Okay. And did anyone other than your attorneys assist you in preparing the report?
A. No.
Q. And you said earlier, I think, that you didn't consult with any of the other experts in the MDL litigation in forming your opinions or preparing your report?
A. That's correct.
Q. And you didn't review any draft reports from any other experts in this litigation?
A. No. The only time I saw their reports was after we had all turned them in to the court.
Q. Okay. And are all of the words, the ideas, the analysis that's contained in

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Exhibit 14, your expert report, are they solely the product of your own work?
A. Yes. I wrote the report. Certainly, again, there were drafts that went back and forth. There may have been suggestions from attorneys where language was -- that I accepted into my report; but yes.
Q. Okay. You didn't borrow language from other experts or from other publications and then not quote that in your report?
A. I certainly tried not to. No. I certainly cited anything that I -- I tried to cite everything that I referenced --
Q. Okay.
A. -- to the best of my ability.
You know, again, I was taking the notes as I wrote, so it's plausible there might be something, but I was very cognizant of trying not to -- trying to cite everything that I was referencing.
Q. And in reaching your opinions, was it important to you that you review the data in a fair and objective way?
A. Yes. I think it's always important to review data in a fair and objective way.

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Q. I know. It's kind of a basic question.
When you were doing your literature reviews and searches, were you looking both for papers or data that supported talc and ovarian cancer connection as well as for data and literature that did not or that -- well, that did not support?
A. When I was doing my literature search, I was looking for any data that spoke to talcum powder products and ovarian cancer. I was really trying to cast as wide a net as possible to get as much data as I could.
Now, certainly, there are limitations when you're doing searches. It's possible there are studies that I missed; but when I was retrieving studies, reading them, I would also reference their references as a sort of cross-check. So I tried to be as complete as I could.
Q. So when you were reading someone else's work and they referenced an article as the basis for synthesis or the statement in their paper, did you then go and review the underlying reference as well?
A. Yes. I pulled up those references.
Q. Okay. And you reviewed those as well?

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A. Yes.
Q. Okay. And you mentioned on Page 4 of your report that your interest in talc and ovarian cancer began during your training, your fellowship training, at Mass General; is that right?
A. I became aware of it. I mean, both Dr. Scully and Dr. Bell were still there at my time of training, and Dr. Scully was a coauthor on Cramer's first 1982 paper.
And then Dr. Bell was a coauthor in one of the subsequent -- I think his 1992 paper with Harlow.
So I was certainly aware of literature on talcum powder and ovarian cancer.
Q. And neither one of them published anything else on talc; is that correct?
A. I believe those were the only two that they were on. That's correct.
Q. And did you understand that the role that Dr. Scully played on Dr. Cramer's first publication was simply that of pathologist and determining or confirming the diagnosis of the samples that were being studied?
A. I was aware that he did a pathologic

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review of the case.
Q. Okay. Did you ever have an opportunity to talk to Dr. Scully about talc and ovarian cancer?
A. I believe my conversations were -- my memory is -- this is 20 years ago now -- it's possible, but probably with Dr. Bell, more. I interacted more with Dr. Bell than Dr. Scully.
Dr. Scully was semiretired at the time. He would come in for half the day, but that was usually when I was with other attendings. But I did spend a significant time with Dr. Bell, and I do remember being aware of that literature.
Now, if you're going to ask me the specific conversation, I probably can't prompt that at the moment.
I was also, when I was at Beth Israel Deaconess, my colleague Jonathan Hecht is there. And I was aware he was doing work on the Nurses' Health Study.
We didn't -- I can't remember if we really talked about talc at that point because the Gates 2010 paper that he was doing, talc was a very small -- it was almost, like, a side comment in that report. But I think we had talked about --

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I know we talked about the Nurses' Health Study.
That's funny, though, I actually did talk -- I saw Jonathan last night, so it's kind of funny timing. But anyway...
Q. Have you talked to Dr. Hecht since then, since you first discussed with him the Nurses' Health Study?
Have you spoken with him on talc and ovarian cancer?
A. Yes. I saw him last night. We went out for a drink.
Q. Did he give you any opinions on what he thought about talc and ovarian cancer?
A. He told me that he had met with defense counsel at one point; did not want to do medical expert witness work but did a brief sort of intro, I guess, overview for the defense.
Q. Did he tell you what his personal or his professional opinion was on whether or not talc causes ovarian cancer?
A. Yes. He thought that -- so I'll say in my report, I did not spend a lot of time on migration because in the gynecologic world, it's widely accepted that migration happens. He told me that he specifically told the defense counsel

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he met with not to use migration because it's widely accepted that it occurs.
We did talk about the Nurses' Health paper. He said that the data set was very small, it was very difficult with classification, and that that -- there just really wasn't a lot of data in that 2010 study.
And he thinks that it is plausible for talcum powder to cause ovarian cancer.
Q. Have you spoken to any other pathologist or colleagues about talc and ovarian cancer?
A. I have talked to my coworkers about it because -- as a conflict-of-interest notification for our group and for our hospital, Partners Healthcare, and I discussed my findings with my partners.
And I've also talked about it at multidisciplinary conferences; recently at, for example, at a thoracic conference. There were gyn oncs there and radiologists and rad onc people there.
Q. And you talked to them specifically about talc and ovarian cancer?
A. So I told them about my work on it and

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the research that I had done, and I was asking them -- it was a thoracic conference, so I was curious if any of them had asked any of their mesothelioma patients that didn't have nonasbestos exposure if they've ever asked them if they'd had talc exposure.

And they said no, they hadn't really done it, they hadn't thought about it, but maybe it was something that they should be asking.

Q. And, by the way, what were the circumstances under which you and Dr. Hecht had dinner the other night?

A. His birthday is coming up. We're still friends, so it was one of these -- I actually stayed in a hotel last night because it took me an hour and a half to drive from Topsfield yesterday morning, and I didn't want to be worried about traffic. So I decided to stay in a hotel last night. His birthday is coming up, so I said, "Let's just grab a drink."

Q. You mentioned while you were at Mass General, the fellowship director for your program was Robert Young; correct?

A. Yes.

Q. Is he someone that you look up to as a

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pathologist?

A. Yes. He's very well-respected.

Q. By the way, who do you send second opinion consults to when you have a difficult case?

A. We have a relationship with Mass General, so I'll occasionally send -- if I need another set of eyes on, I'll send it to either -- it's sort of their gyn pathology group in general, so it might be Dr. Young. It might be Esther Oliva. Those are the two that I would say most frequently would receive any consults from our group for gyn path.

Q. Have you ever spoken with Dr. Young about talc and ovarian cancer?

A. It's possible. I haven't recently. He and I aren't in regular communication, so I certainly wouldn't have talked to him -- I don't know if I've talked to him since starting this.

It's more of a professional-type relationship, so I don't know if it would have come up recently. But it's possible in training, but I don't remember specifically.

Q. And Robin Young inherited all of Dr. Scully's case files in his office when

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Dr. Scully retired; is that right?

A. Yes. He inherited his consult service. So it's a separate service from our regular clinical work. So it's pathologists from all over the country or even world that have difficult cases, they will send as a specific private consult to -- it was Dr. Scully, and now it's Dr. Young.

Q. Okay. When you were first contacted by the plaintiffs' counsel back in 2017, what were your opinions regarding talc and ovarian cancer at that point?

A. First contacted? When I was first contacted, I was aware of the literature, certainly. I hadn't come to a strong opinion one way or the other. In fact, I'd probably say I was aware that the epi data had been relatively consistent. That was kind of all I knew about it until I did my sort of deep dive into the literature for my general causation opinion.

Q. So as a pathologist, you never had a particular interest in pursuing additional research in the area --

MR. ROTMAN: Objection.

Q. -- of talc and ovarian cancer?

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A. Well, there's certainly a lot of things to study in gynecologic pathology. And so I hadn't decided to take that -- to do that study at the time that I was contacted by counsel. That's not to say I never would have or I never would have thought about it, but I hadn't at the time.

Q. Okay. In your report on Page 4, you say that you've maintained a professional interest -- "since your fellowship, you've maintained a professional interest and have continued to monitor developments in the science regarding talcum powder exposure and ovarian cancer, and it has been the subject of professional discussions predating the litigation."

So what sort of professional discussions about talc and ovarian cancer did you have before the plaintiffs retained you?

A. So, again, I was aware of the literature. And I knew -- I saw some of the newer epi data come out. I had had conversations with Dr. Bell that I remember specifically; again, with Jonathan. I knew he was working on that Nurses' Health. We certainly talked about

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that study at some point.
But, you know, I was certainly aware of the literature as it came out.
Q. And you call it a "professional interest."
Did you take -- other than just reviewing the literature, did you do anything professionally to either advance your knowledge or other people's knowledge about this potential association?
A. Not -- I mean, not at the time. I think "professional interest" in my mind, you know, means being aware of what's going on in the literature. Again, that doesn't necessarily mean an in-depth review of everything but being generally aware of it.
Q. Would you say that since you first learned about this in your fellowship and were interested in the topic, did it influence the way you looked at gynecologic cases as a professional pathologist?
A. Yeah. It's not really routine practice to use polarized light microscopy in gynecologic pathology. It's just -- we use it more commonly for breast cases, so...

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And also, you know, even if we found birefringent particles and granulomas or -- in the tissue, it wouldn't necessarily mean that they're talc unless you do subsequent studies.
So I wouldn't say it changed my daily practice in diagnosing tumors.
Q. Okay. Doctor, if you can turn to Page 4 and 5 of your report.
Is this where you set out a summary of your opinions?
A. Yes. This is.
Q. Under Heading 2, Page 4, "General causation opinions."
A. Okay.
Q. And you list, it looks like, five specific opinions; is that correct?
A. I see where you are. Yes.
Q. And are those -- again, are those all the opinions that you have that you intend to offer in this case?
MR. ROTMAN: Objection.
A. Same answer as before. Again, there might be something that comes up today or at trial that I'm asked that I, you know, didn't put in this report. But I tried to be as -- complete

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in the report.
Q. Okay. And the first opinion is that talc can migrate to the ovaries through the genital tract through the lymphatic system and through inhalation.
Is that an accurate summary of your first opinion or set of opinions?
(reading from document)
A. Yes. The talcum powder products can reach the ovaries; that they can be transported through the lymphatic system; and there is evidence that it can be inhaled as well with transport to the ovaries.
Q. And the second opinion in the case or second set of opinions is that talc causes chronic inflammation in the ovaries, causes increased oxidative stress in the ovaries, and causes immunosuppression.
Is that an accurate summary of your mechanism?
A. Well, if you're going to read it word for word, it's "Once reaching the ovaries, talcum powder products can cause chronic inflammation, can increase oxidative stress, and can reduce immune response. These are biologically

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plausible and likely mechanisms for ovarian cancer development and progression."
Q. Okay. When you say "reduce the immune response," is that essentially discussing, like, an immunosuppressive effect?
A. That's referencing the MUC-1 antibody paper that Cramer published in 2005.
Q. Are you aware that Dr. Cramer himself has disclaimed that theory as a "hypothesis that's not ready for prime time"? I believe those were his words, "prime time."
A. I don't know where you saw those words.
Q. His testimony in the litigation.
A. Okay. I don't believe I saw his testimony in the litigation. But, again, it's not -- I'm not seeing it as something that needs to be proven. I'm looking at it as a plausibility that, you know, it's a plausible mechanism. If it's not proven, it doesn't really change the fact that it's plausible.
Q. So are you building -- so is your plausibility opinion independent of whether or not the basis for that opinion is proven?
MR. ROTMAN: Objection.
Q. In other words, are you -- do you have

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a plausibility opinion that's based on a bunch of other potential or plausible mechanisms?
MR. ROTMAN: Objection.
A. Right.
MR. ROTMAN: I just objected, but you can answer. If you can understand the question, you can answer it.
A. Well, I think -- I think they're all somewhat interrelated.
I think there's the chronic inflammation. There's the immune response. Those are plausible mechanisms for ovarian cancer.
And the Bradford Hill guidelines, you don't have to prove -- prove mechanism in order to have causation. We have plenty of -- again, plenty of examples of that in prior diseases, like smoking and lung cancer. And even certain drugs, they don't know the mechanism of action, very common drugs like lithium, for example, or metformin.
So you don't need to prove mechanism in order for it to be an important part of a causation because it's part of the plausibility component.
Q. Do any of the bases on which you -- any of the bases that you use to support plausibility

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for talc and ovarian cancer, do any of them have to be proven or established?
MR. ROTMAN: Objection.
A. I think it's important to have evidence to support it. There may be evidence that refutes it as well, but you're sort of looking at -- you're balancing the weight of it.
And the plausibility, a plausible mechanism, now, is that always going to be probable or definite? No. It's plausible.
In this case, I think it's a compelling mechanism, chronic inflammation, because, again, we know that talcum powder can reach the ovaries, and we know that it can cause chronic inflammation, and we know chronic inflammation is implicated in cancer.
So I think it's a high degree of plausibility in that case.
Q. So when you mention that you know that talc can reach the ovaries, are you referring to, for example, the Heller study?
A. So Heller found talc in women's ovaries. Yes. Cramer found talc in pelvic lymph nodes. We have other animal and human studies of talc or particulates similar in size to talc

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reaching the ovaries.
So -- and, again, it's widely accepted in the gynecologic community that migration occurs. In fact, endometriosis, we really -- the evidence is that endometriosis is caused by retrograde menstruation of endometrium.
So there's a substantial amount of evidence and widely accepted that migration occurs.
And I'm aware of studies that didn't find migration, but I think, you know, those few negative studies don't cancel out the positive studies.
And, you know, certainly, looking for migrated particles is very difficult. You know, again, we're talking about dose. How much do you inject to get there?
And so I think the positive studies are compelling, and it's widely accepted that migration occurs.
(Article entitled "Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc" marked Exhibit 19.)

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BY MS. AHERN:
Q. Doctor, I'm handing you what's been marked as Exhibit 19 to your deposition.
A. Okay.
MR. TISI: Thank you.
MS. AHERN: You're welcome.
Q. Exhibit 19 is an article drafted by Dr. Dan Cramer, the "Presence of talc in pelvic lymph nodes of a woman with ovarian cancer and long-term genital exposure to cosmetic talc."
Is this a paper that you were referring to a few minutes ago?
A. The 2005, yes.
Q. This is 2007.
A. I'm sorry. Did I say 2005? Yes. This is the paper, anyway.
Q. And the authors are Dan Cramer and Bill Welch, Ross Berkowitz, and John Godleski.
Do you see that?
A. Yes.
Q. And three of those individuals have been disclosed as plaintiffs' experts in the talc litigation.
Were you aware of that?
A. I was not aware of Bill Welch. I knew

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after -- at some point, I was aware that Dr. Cramer and Dr. Godleski was. I don't believe I was aware of that at the beginning of my research, but I became aware of that. Yes.

Q. Okay. Are you aware that Dr. Welch has been designated in maybe three cases and given testimony in those cases?

A. Again, I was not aware that Bill Welch had been retained.

Q. Are you aware that Dr. Welch has run the pathology portion of Dr. Cramer's study program for 40 years?

A. I'm aware who Dr. Welch is, and I've certainly seen his name on papers. But now his -- his role in these studies specifically, I don't know if I can speak to other than he's involved.

Q. He's testified that his only role was in identifying the types of tumors involved in the study to keep people honest.

Are you aware that Dr. Welch has repeatedly refused to give -- refused to give a causation opinion like you're giving today?

A. I'm not aware of Dr. Welch's opinions. I didn't know that he was an expert, so I

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wouldn't have reviewed any of that testimony.

Q. Okay. You weren't provided with any of his testimony or his reports in the litigation?

A. No. I was not aware that he was a medical expert witness.

Q. Okay. Do you see under the "Background" section here, it says, "Although epidemiologic studies suggest talc may increase ovarian cancer risk, there is no proof that talc used externally reaches the pelvis"?

A. That's what it says.

Q. Are then if you look down in the -- I'm sorry. I'm sorry.

If you look down in the first paragraph, he mentions, "An epidemiologic association between the use of cosmetic talc and genital hygiene and ovarian cancer was first described in 1982."

That's Cramer citing Cramer; isn't it?

A. Let's see. Let me double-check. I'm assuming because it's 1982. But let me double-check. Or -- yeah. It's 1999. He's referencing his 1999 paper.

Q. And he says, "And the many subsequent studies found talc use to increase the risk for ovarian cancer."

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A. I'm sorry. Where are you now?

Q. Same sentence. He just finishes it with "Many subsequent studies found --

A. Okay.

Q. -- "talc use to increase the risk for ovarian cancer."

But he just cites himself again from 1982; correct?

A. Sorry?

Q. The only cite he provides for that statement is his own study from 1982?

A. Oh, the one -- the No. 1?

Q. Mm-hmm.

A. Yes. That's his 1999, it says. 1999.

Q. Okay. Sorry about that. You're right.

And then he says, "However, the causality of the relationship has been challenged for several reasons."

Do you see that?

A. I do.

Q. And he says, "First, the association is a relatively weak one; i.e., summary relative risk of approximately 1.3."

Do you agree that a summary relative risk of 1.3 is a weak association?

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A. I've seen "weak" or "moderate" used to describe a 1.3, but that doesn't mean it's not a significant one, especially in a rare disease like ovarian cancer.

MS. AHERN: Objection to the nonresponsive portion.

Q. But I agree it's been described as "weak," at least here by Dr. Cramer?

A. That's -- the sentence says, "First, the association is a relatively weak one; i.e., summary relative risk of approximately 1.3."

Q. And he says, "Second, there's no clear increase in risk with duration of use."

Do you agree with that, as of 2007, there was no clear dose-response in the studies that looked at talc and ovarian cancer?

A. I think there was evidence of a dose-response by 2007.

Q. So do you disagree with Dr. Cramer's statement in the 2007 publication that as of that time, there was no clear increase in risk with duration of use in most studies?

A. I wouldn't necessarily phrase it that way: There's no clear increased risk. I think, again, there isn't a lot of data, but what data

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there was -- I believe at that time, I'm trying to think if I was in 2007 -- would be evidence that there was a dose-response.

Q. And which papers, prior to 2007, did they find dose-response that was clear?

A. I would have to look back.

Okay. So I tried to do this in chronologic order.

Q. What page are you on?

A. I'm looking at 16.

Q. Page 16 of Exhibit 14?

A. Yes.

Q. Okay. Were --

A. I'm just trying to refresh my memory.

So Harlow's -- let's see -- 1992 study was, it looks like, the first one that I have listed that had a dose-response -- evaluated for dose-response.

They both -- let's see. The confidence intervals all included the null. Life- -- so what I wrote here -- this is Page 18 -- "lifetime application ORs when compared to control women with no perineal talc exposure were 1.3, 4 less than 1,000, with a confidence interval of 0.7 to 2.7; 1.5 for 1,000 to 10,000 with a confidence

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interval of 0.9 to 2.4; and 1.8 for greater than 10,000 with the confidence interval of 1.0 to 3.0.

And then I also -- yeah. So that's after 2007, the Terry and the Lou studies.

Q. You're looking at Harlow 1992?

A. Yes. That's the paragraph I'm looking at.

Q. And Harlow 1992 found a nonstatistically significant increased risk; is that correct?

A. So the confidence intervals included the null. So, yeah, it was not statistically significant. I'm not sure -- I don't have the numbers here, though, of how many they had dose-response data on, which would -- which might increase the interval.

In fact, if you look at the confidence intervals, they're pretty wide, trending toward higher.

Q. What are the confidence intervals you're looking at?

A. For less than 1,000 lifetime applications, we're looking at 0.7 to 2.7.

For 1,000 to 10,000, we're looking at 0.9 to

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2.4.

And for greater than 10,000, we're looking at 1.0 to 3.0.

Q. And when they just adjusted -- when they excluded -- when they looked at lifetime talc applications and ovarian cancer after excluding use following hysterectomy or tubal ligation, they found no evidence of an exposure-response relationship, didn't they?

A. Are you looking at the actual paper?

Q. Do you need it?

A. If you're asking me questions about it.

Q. Yeah. That wasn't in your report -- or is it?

MR. ROTMAN: What is the "it" referring to?

Q. That particular finding is not in her report on dose-response from Harlow in 1992?

A. Well, yeah. Let me look at the --

MS. AHERN: Sure.

(Article entitled "Perineal Exposure to Talc and Ovarian Cancer Risk" marked Exhibit 20.)

MS. AHERN: I'll mark as Exhibit 20 to your deposition "Perineal Exposure to Talc and

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Ovarian Cancer Risk" by Harlow, 1992. That's my only copy. Sorry.

MR. ROTMAN: Exhibit 20.

A. Okay. So, I'm sorry, where are you looking?

Q. Let me find it. Take your time, if you need to. I'm trying to find my copy.

Okay. If you look at Table 3, "Estimated total lifetime perineal applications of talc containing powders and cases and controls."

A. Okay. I see Table 3.

MR. ROTMAN: Is there a question?

MS. AHERN: She asked to see the study. I asked her to confirm that once they excluded cases after hysterectomy or tubal ligation, there was no exposure-response relationship.

A. These look to be similar -- oh, I see. Okay. Total applications.

Well, if you actually look at the numbers, the ones above, which are, I believe, what I quoted in my report, so under "Total applications."

And then you're asking me about applications excluding use after hysterectomy or tubal ligation?

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BY MS. AHERN:
Q. Mm-hmm.
A. What was your question about it? I'm sorry.
Q. There's no statistically significant dose-response relationship with lifetime application?
A. So the confidence intervals are somewhat similar, but -- are somewhat similar, it looks like, to the top.
Q. There's no statistically significant dose-response relationship, is there?
A. They all include the null. That's correct. But, again, they're trending high.
Q. But if they include the null, then it's consistent with the null hypothesis that there's no association; isn't that true?
MR. ROTMAN: Objection.
A. It's possible. The null hypothesis is included in "Possibilities."
Q. It also basically means you can't exclude chance as a reason for the findings; correct?
A. Again, it's possible. I would say it's trending higher, but it does include the null

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hypothesis.
Q. Do you see on Page 25, in the first column on the left-hand side, the first full paragraph, "In our analysis"?
Okay. The authors say, "In our analysis, we first calculated all genital applications of talc based on frequency and years of use. As a continuous variable in a multivariate model, no significant dose-response was observed between total genital applications of talc and ovarian cancer risk"; correct?
A. That's what it says.
Q. And the reason they excluded hysterectomy and tubal ligation is the next sentence, "because the translocation theory assumes an open genital tract, we then excluded application after tubal ligation or hysterectomy but observed no appreciable change in the dose-response."
In other words, still no significant dose-response; correct?
A. That's what it says.
Q. So the authors interpreted both the data you cite in your report as well as the data you didn't cite in your report as showing no

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dose-response?
A. Well, I state in my report what the confidence intervals are. So certainly, I'm showing that it did include the null hypothesis. But I think it's still -- just because it's not statistically significant, I think it's still data, and I wouldn't completely discount it.
But it does -- does contain the null. The numbers weren't super high, if I remember. But on their -- I'll have to find it.
On -- in their abstract conclusion, they still say that "The greatest ovarian cancer risk associated with perineal talc use was observed in the subgroup of women estimated to have made more than 10,000 applications during years when they were ovulating and had an intact genital tract with the OR of 2.8 and a statistically significant confidence interval of 1.4 to 5.4. However, this exposure was found in only 14 percent of the women with ovarian cancer."
Q. Okay. But we were just asking -- you mentioned the study as support for a dose-response relationship in your report?
A. As evidence of a dose -- a dose-response; again, with the caveat, which is

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here, that it includes the null hypothesis.
Q. Okay. And what about Cramer in 1999?
MR. ROTMAN: Objection. I don't think that's a question.
MS. AHERN: Fair point.
BY MS. AHERN:
Q. In Cramer 1999, you've also cited as evidence after dose-response, correct, on Page 35 of your report?
A. I see that. Yes. It's listed in a reference list.
Q. And the authors, including Cramer, basically say they "failed to demonstrate consistent dose-response relationships with measures of intensity of exposure."
MR. ROTMAN: Do you have -- do you have the paper?
MS. AHERN: Do you want the paper?
MR. TISI: Is that the one you identified before?
MS. AHERN: No. This is a new one.
MR. ROTMAN: She's getting the paper out.
MS. AHERN: I thought I had it too. Maybe it's in one of the boxes. Let me see if I

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can find my own copy.
Okay. Sorry. This is the only copy I have right now.
THE WITNESS: Okay.
MS. AHERN: We can mark it, if you want.
BY MS. AHERN:
Q. It's a copy of the Cramer 1999 publication that you cited in your report in support of dose-response.
MR. TISI: Are you marking it?
THE COURT: I can if you want me to. I just didn't want to mark my copy.
MR. KLATT: I don't think I do.
MS. AHERN: That's all right. I don't. We'll mark Cramer -- oops, no, we won't because this is the wrong study. Sorry. The old "wrong study" trick.
THE WITNESS: I can't find that information. Oh, I've got the wrong reference. Sorry. All righty.
(Article entitled "Genital Talc Exposure and Risk of Ovarian Cancer" marked Exhibit 21.)

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BY MS. AHERN:
Q. Okay. So, Doctor, this is Exhibit 21, which is "Genital Talc Exposure and Risk of Ovarian Cancer," Dan Cramer, 1999.
A. Okay.
Q. This is something else.
Can you find -- I don't have it in front of me, so I'm going to rely on you to find the tables that show their dose-response analysis.
MR. ROTMAN: You made that Exhibit 21?
MS. AHERN: Yes.
MR. TISI: It's 21. Yes.
THE WITNESS: Would that be Table 2, what you're referring to (indicating)?
BY MS. AHERN:
Q. I believe the numbers were -- they were looked at in terms of zero years' duration, less than 20, 20 to 30, and greater than 30.
Do you see that on there?
A. I'm looking. This one says "less than -- frequency of use."
Q. There's a frequency and a duration.
A. Okay.
Q. Yeah.
A. Sorry. Why am I not seeing it? It's

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in the table. Let me see.
Q. I think so. If you want to go to --
A. Oh.
Q. You got it.
A. Yes. I see it now. Sorry. It was buried in Table 3, very small print. Okay. Yes.
So Table 3, years of use. Yup.
Q. Do you see they're not showing a statistically significant dose-response relationship?
A. So for less than 20 years, the confidence intervals were 1.16 to 3; at 20 and 30 and greater than 30, they did -- the confidence intervals did include the null.
But, again, I don't know how many -- I can't remember. Oh, here are the cases.
Yeah. So there are 55, less than 20 cases; thirty-two 20 to 30; and 59 greater than 30.
Q. And you see also the frequency analysis? It also did not find a significant dose-response relationship as a statistically significant dose-response relationship?
A. Yes. For less than 30 years, the adjusted OR was 2.21 with a confidence interval of 1.37 to 3.56.

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The 30 to 39 was adjusted OR of 1.17 with confidence intervals .78 to 1.76.
And the 40-plus adjusted OR was 1.57 with confidence intervals of 0.8 to 3.10.
Q. So not only did the point estimate go down with more use, but the higher the concentration, there was also no statistical significance; correct?
A. Yeah. I mean, the numbers -- so the only one that doesn't include the null -- let me just double-check.
Actually, there are two. So the less than 20 years or less than 30 per month are statistically significant.
Q. It's only the first dose category in each group --
A. Yeah.
Q. -- shows statistical significance.
And as the doses got higher, the exposure frequency got higher, the point estimates went down and statistical significance went away; correct?
A. The confidence intervals did include the null. And I think this illustrates how difficult sort of dose and frequency can be to

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study because we don't really know what the doses are, and we don't really have granularity as far as frequency of use. Well, I have to look at --

Q. These are studies that you cited in your report as evidence of a dose-response, correct, the Harlow and the Cramer papers? You both cited yourself.

Did you evaluate the internal validity of those studies and critically evaluate the methods and study populations when you included them in your report?

A. Let me -- well, I said -- this is the sentence -- "Most have found an increased risk of ovarian cancer with increased exposure." So, yet, when studies have evaluated duration of frequency of perineal talc use.

So this list is the studies that evaluated duration and frequency of perineal talc use. And I said, "Most have found an increased risk." So what I'm citing here are the studies that looked at duration and frequency.

Q. Okay. And we were referring to Cramer's 2007 publication where he himself says that the association has been challenged because it's weak and because there's no clear increase

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in risk with duration of use.

And you didn't agree with that statement, and you referred me to Harlow 1992; correct?

A. I was going to where I mentioned the dose-response studies.

Q. Okay. Just to button up and finish up with Cramer 1999, if you look at Page 355, the authors included, "They failed to demonstrate consistent dose-response relationships with measures of intensity of exposure."

Do you see that?

A. I'm sorry. Where are you?

Q. On Page 355.

A. Okay. I'm seeing "in attempting" -- sorry. I see, "Most talc and ovarian cancer studies that have addressed dose-response, including this one, have failed to demonstrate consistent dose-response relationships with measures of the intensity of the exposure, especially when the trend is examined among users only. In attempting to address this weakness, we point out that it is difficult to quantify the amount of powder actually used and degree of perineal dusting that might constitute an application of talc," quote/unquote around

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"application of talc."

"Another factor that may affect the dose-response relationship is whether use occurred at a time when the female tract was open. There is evidence from several studies that the talc/ovarian cancer association is modified by closure of the female tract as a result of tubal ligation or hysterectomy.

Q. Doctor, did they say they didn't find a dose-response relationship?

A. I'm trying to find what they said other than that on Page 355.

Yeah. They said, "Studies that have dose-response, including this one, have failed to demonstrate consistent dose-response relationships."

But it goes on to qualify with the difficulty of measuring dose and frequency, which is what I described earlier.

Q. Mm-hmm.

(Article entitled "Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California" marked Exhibit 22.)

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BY MS. AHERN:

Q. Okay. The next one -- are you done, sorry, with that one?

A. If we're moving on, sure.

Q. If you're done.

The next one you mention, you cite in your report for dose-response is Mills 2004, which I'm handing you now marked as Exhibit 22.

Oh, yeah. We'll leave that here for right now.

A. Okay.

MR. ROTMAN: Can I see the one you just finished with?

MR. TISI: This is 22; right?

MS. AHERN: Yes, sir.

BY MS. AHERN:

Q. And this one, you're welcome to read through it if you want. All I wanted to point out is if you look right up front in the abstract, a little more than midway down, they say, "The odds ratio for ever use of talc was 1.37 with the confidence interval of 1.02 to 1.85 compared to never users. However, no dose-response association was found."

Do you see that?

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A. I see where it says that.
Q. And if you want to look through there and convince yourself of that, go for it. I think the table that we're looking at is Table 2 on Page 460.
A. Yeah. The 4 to 12 years had an OR of 1.86 that was statistically significant at 1.16 to 2.98. But the others, which were never -- which, of course, is the null, 4 to 12 years, which -- oh, the 13 to 30 was adjusted OR of 1.45, confidence interval .9 to 2.32.
And then the greater than 30 years was OR of 1.22 with confidence interval of .72 and 2.08. So the 13 to 30 and the greater than 30 includes the null.
And then if we look at frequency, cumulative use, frequency types duration, there was a statistically significant increase with second quartile and third quartile divisions. But then it dropped in the fourth quartile, the highest exposure.
And, you know, again, sort of difficulty in measuring this. But you do see an increase in the second and third quartile, between the second and third, that was statistically significant.

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And then --
Q. But the authors themselves interpret their data as no dose-response association; correct?
A. In the abstract, that's what they state. I'm trying to figure out what their -- what they said. They must have said a little bit more.
Q. Doctor, you reviewed this study before; right?
A. I did. Yes.
Q. Okay.
A. I'm just refreshing my memory.
Q. Okay. If you look at Page 463.
MR. ROTMAN: Are you changing the topic?
MS. AHERN: No. Same topic.
MR. ROTMAN: She was looking for something as part of a prior answer.
BY MS. AHERN:
Q. As part of your prior answer that there was no dose-response?
A. As part of the answer that they stated that in the abstract. I was trying to find out where they had a discussion.

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Q. I was trying to point you a little bit toward this. It's Page 463. There's some discussion of it.
If you look at the third paragraph down, "As in other studies, the present study did not find a clear dose-response based on duration of use or cumulative use."
And then it says, "Limiting the analysis of dose-response to women who reported ever use of talc did not affect the results, data not shown. The lack of dose-response between talc use and epithelial ovarian cancer may be explained by the inability to quantify the actual amount of talc used per application and the timing of the application."
A. Yeah. So with that caveat.
Q. Well, the findings are what they are; right?
The findings are no dose-response relationship?
A. The findings are what they are. But, again, it's not an easy -- there's not huge numbers in these cases.
And, again, you still don't know from woman to woman what one dose is, so there's a ton of

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variability. It's not like a cigarette, where, you know, from one cigarette to the next or, you know, a drug dose is probably a more accurate analogy, you know.
Q. True. But just because it's difficult to study, it doesn't mean if we could study it better, we would get a positive result, does it?
A. I -- oh, my thing is not working. I think I have to plug my thing in.
MR. ROTMAN: Can you?
COURT REPORTER: I'd have to break to do it.
MR. ROTMAN: Let's go off the record.
THE VIDEOGRAPHER: Off the record. 4:37 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Back on the record, 4:44 p.m.
BY MS. AHERN:
Q. Okay. Doctor, you saw the Mills paper in front of you?
A. Yes.
Q. Okay. Could you look at your report on Page 21?
(Witness complies.)

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A. Okay.
Q. Let's see, where is my copy?
And turn to Page 3 of the Mills publication.
A. Page 3, which would be Page 460?
Q. That's a good question.
Where is my Mills publication?
MS. AHERN: Do you have it?
MR. TISI: Sure.
MS. AHERN: Thank you.
Oh, I know where it is.
BY MS. AHERN:
Q. I'm sorry. I thought I had the specific passage marked. And I do, somewhere in here. Okay. Sorry. It's on Page 460. I apologize.
A. Okay.
Q. All right. Do you see on the Mills publication on Page 460 that bottom paragraph on the left, "ever use of talcum powder"?
A. Yes.
Q. And if you read down toward the bottom part of that paragraph, on the fourth line from the bottom, the sentence starts "Duration of use."
A. Okay.

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Q. "Duration of use of talcum powder was associated with increased risk, although the pattern was also not clear-cut in that the point estimate peaked among those reporting 4 to 12 years of use and declined somewhat among those reporting longer duration of use."
Do you see that statement?
A. I see that. Yup.
Q. And if you look at your report on Page 21, the top paragraph, about midway, a little -- well, a third of the way down, you pick up with "Duration of use of talc was also associated with increased risk, although the risk peaked."
Do you see that statement?
A. Yes.
Q. If you compare those statements, are they almost identical with the exception of the statement by Mills that the pattern was not clear-cut?
A. They are similar. This might have been, like I described earlier, where, if I was taking notes, some of the language might have gotten incorporated, although I do have the citation.

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Q. Is there a reason that that entire portion of your report is copied identically from Mills except for the qualifier that the pattern was not clear-cut for dose-response?
A. Well, I think it still has the same meaning.
Q. Without the qualifier?
A. I think the qualifier is in the -- in the data.
Q. Okay.
A. I don't think I was -- I wasn't trying to make it sound anything different than what it was. I think I was trying to report the data.
Q. Okay. All right. And, Doctor, if you turn to Page 10 of your report, the section on inflammation.
Are you there?
A. Yes.
Q. You start on the second paragraph under "Inflammation" discussing oxidative stress.
A. Okay.
Q. Okay. Were you aware that a significant amount of the section of your report on oxidative stress is copied verbatim? More than 60 percent of it, I think, is copied

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verbatim from Dr. Saed's 2018 publication?
A. Again, if the language is similar, it was not an intentional. I am citing him here, so it's -- you know, it's clear that those are the references. Again, it might have been due to note-taking, but the citation is clear.
Q. Do you ever take verbatim language out of another scientist's work and not set it off in quotation marks in your professional work?
A. I think I've cited the source here. It's -- so it's not -- again, it's not like I was intentionally copying his words. It was, again, probably an editing while I was taking notes, but the citations are clear.
Q. Is your -- is the underlying understanding that you have related to oxidative stress and inflammation drawn primarily from Dr. Saed's work?
A. No. I mean, oxidative stress and inflammation is something that we study -- that I've studied.
Q. Have you ever published a study on oxidative stress or redox biology?
A. I have not published on oxidative stress.

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Q. What sort of work as a pathologist have you done that incorporates redox biology?
A. Well, again, this is part of our medical training. Certainly in training to be a physician, that is something that we learn. And, you know, pathologists do quite frequently come across inflammatory -- inflammation literature.
Q. Are you -- is it your position that the information in your report under "Inflammation" that discusses oxidative stress and redox biology is common knowledge among pathologists?
A. That oxidative stress and inflammation, yes. I think -- yes. I think that's widely accepted.
Q. The specific information contained on Pages 10 and 11 of your report that was drawn from Dr. Saed's work, is that information that is common knowledge?
The specific enzymes that are discussed, the research on these issues, is that specific information there common knowledge?
A. It's common knowledge that these types of cancer are associated with inflammation, and certainly oxidative stress is part of inflammation.

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Q. Was this common knowledge to you before you reviewed Dr. Saed's 2018 publication?
A. Yes. I was just citing his report at this point.
Q. Are you aware you also cited his underlying citations in the same spots that he cited them?
A. That's possible because I reviewed his citations as I was reading his citations.
Q. Did Dr. Saed give you permission to copy his -- the language from his publication?
A. I wouldn't characterize it as "copying." I think it may be similar language, again, because I was writing as I was reading. But I am certainly clearly citing his work and the other citations.
Q. Do you agree that Dr. Saed's 2018 paper is a compilation of his own synthesis and review of the underlying articles that he incorporated into his paper, and do you think it's appropriate for you to just lift the language from his paper and the citations that he found and synthesized and put it in your report and not attribute it to him with quotation marks?
MR. ROTMAN: Objection.

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A. I did attribute -- I certainly cited him in several places in this area. And, again, it was not an intentional copying. Again, it might have just happened with my editing, but I certainly tried to cite everything that I was looking at in the proper place.
But I do believe that it's common knowledge that chronic inflammation can cause different types of cancer. This is not really new data.
Q. Dr. Saed says that it's new data.
A. In what respect, though? If we're talking about myeloperoxidase, yes. But I'm talking about oxidative stress and chronic inflammation with known association with certain types of cancer.
Q. So it's your testimony that the verbatim text that you used in the section from Dr. Saed's 2018 paper was appropriately cited and attributed to him?
MR. ROTMAN: Objection.
A. Again, I'm not sure it's absolutely verbatim, but I certainly cited him in every place that I was referencing.
Q. Okay. We'll just move on.
(Highlighted copy of Dr. Kane's

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expert report marked Exhibit 23.)
BY MS. AHERN:
Q. Doctor, I've marked as Exhibit 23 to your deposition a highlighted copy of your report that shows the verbatim text that has been carried over from various publications into your report.
If you turn to Page 10 and 11, you'll see that the highlighted portions are copied directly from Dr. Saed's work.
MR. ROTMAN: Do you have a copy for me of this exhibit?
MS. AHERN: Oh. I do. Sorry about that.
MR. ROTMAN: So we're at Page 10 and 11?
MS. AHERN: That's just for the Saed publication. And there's one in there that Saed was also on.
MR. ROTMAN: Does she have the Saed publication in front of her?
MS. AHERN: I can find it for you.
BY MS. AHERN:
Q. But my point is, are you aware that that -- that there's a significant portion of

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that section of your report that is just cut-and-pasted from Dr. Saed's work?
A. I don't believe -- again, it's -- it wasn't intentional with the citations, and it could have happened with my note-taking or other suggested input. But, again, I cited -- I certainly cited him in that section.
Q. Okay.
MR. TISI: Did you mark that?
MS. AHERN: Hmm?
MR. TISI: Did you mark that as an exhibit?
MS. AHERN: Yes. I think it's 23. Sorry.
MR. TISI: That's okay.
MR. ROTMAN: Do you have the Saed in front of you?
BY MS. AHERN:
Q. I think it's -- it wasn't intentional is your testimony, and it's probably just a result of your note-taking process; is that correct?
A. Well, because I cited him specifically, certainly it wasn't intentional to be verbatim. And I'm not sure exactly the process, but

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certainly I'm citing him several times there.
Q. Okay. That's fine. We'll just move on.
And, Doctor, just to be clear, I understand your testimony is that it is common knowledge to pathologists that oxidative stress and inflammation are related; correct?
A. Yes.
Q. Okay. But you are -- we're talking about oxidative stress and redox biology specifically as a field of study or research.
You're not an expert in that field of study or research, are you?
A. I certainly have read literature in that area.
Q. Does that make you an expert?
A. I'm -- I mean, I'm familiar with literature in the area. That's -- that's my answer.
Q. Okay. But you don't conduct studies in oxidative stress and redox biology, do you?
A. I do not conduct studies in oxidative stress and redox biology.
Q. You're not currently participating in a study looking at oxidative stress or redox

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biology and inflammation, are you?
A. I am not currently participating in a study of oxidative stress or redox biology.
Q. You don't have any funding related to oxidative stress and inflammation, do you?
A. No, I do not.
Q. Have you ever applied for any funding in that area?
A. No. I have not.
Q. Have you ever authored a systematic review of the literature on oxidative stress and inflammation?
A. Oxidative stress and inflammation, no. I don't believe I have.
Q. Have you ever authored a systematic review of the literature on oxidative stress and cancer?
A. No. I have not authored a systematic review on that.
Q. Okay. Doctor, moving on to inflammation and ovarian cancer.
Generally, on inflammation, can you cite to a published experiment that was conducted in animals in vivo that establishes a role of any particular inflammatory cell or cytokine or

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enzyme in tumor regenesis?
A. Oh. Let me -- let me bring up my inflammation section. Sorry. I'm just refreshing myself as to what I stated in my report.
Oh, this is low battery again. I don't think this is plugged in.
MR. ROTMAN: Can we take five minutes off the record?
MS. AHERN: Yes.
THE VIDEOGRAPHER: Off the record, 5:02 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Here begins Media No. 6 in today's deposition of Sarah Kane, M.D. Back on the record, 5:28 p.m.
(Article entitled "Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer" marked Exhibit 24.)
BY MS. AHERN:
Q. Dr. Kane, I'm marking what's been -- well, I'm marking Exhibit 24 to your deposition, which is a copy of the Merritt 2008 publication. And I'm sorry, I don't have an extra. I'm going

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to share.
It's "Talcum powder, chronic pelvic inflammatory -- sorry, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer."
And you cite Dr. Merritt's paper a couple of times in your report; is that correct?
A. I believe I cited it, yes.
Q. I think you cite it as a statistically significant positive talc study on Page 17 of your report?
A. Oh, let me get to that, if that's the section I'm thinking of.
Q. There are a couple of places?
A. There was -- yes. This happened in editing. I believe if this is -- so the sentence ended up, it originally didn't have the "statistically significant." It was just, you know, an odds ratio greater than one and listed.
And then I mistakenly didn't delete. When I changed it to "statistically significant," for some reason -- I don't know if it happened in the editing between additions or something -- somehow I seem to remember deleting them. But in the final, they ended up all there. So that was a --

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MR. ROTMAN: What page was this?
A. -- typographical error.
It's in there twice. I noticed it after I submitted it, and it was one of those --
Q. Are you saying Merritt is not statistically significant?
A. So I know which -- again, I'd have -- I have to go through. It's been a long day, and the names are starting to get all confused.
Q. Yeah.
A. But I know that that sentence, with "all of those" at the end of that sentence, is incorrect because I had changed -- I had meant to list cumulatively the statistically significant ones and ended up --
Q. Okay. So just to clarify for the record, on Page 17, we're talking about the first full paragraph that says, "In addition to the Cramer 1982 study, numerous other case-control studies addressing talc use and ovarian cancer have shown statistically significant odds ratios greater than one indicating talc use is associated with an increased ovarian cancer risk."
And then there's a string cite with a number

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of multiple publications.
A. Right.
Q. You're saying that some of those publications shouldn't be in there because you added "statistically significant" as a criteria later?
A. Exactly.
Q. Okay. That's actually not my question about Merritt, but thank you.
A. I knew that was going to come up --
Q. That's okay.
A. -- at some point.
Q. While we're there, since we're sitting here looking at this, so these are -- you listed out case-control studies addressing talc, and they're supposed to be those that have statistically significant odds ratios; correct?
A. That's correct. That was the intention.
Q. And Gertig 2000 is there, and Houghton 2014 are there, and they're obviously cohort studies?
A. So, again, I think that somehow that paragraph got all -- and I didn't catch it in the final edits.

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Q. Okay.
A. I know that that was at least a different paragraph at first, possibly two paragraphs that got condensed. And then somehow, the references didn't get changed in the final.
Q. Okay. Do you happen to know -- and if you don't it's okay -- but do you happen to know which of these studies should be there and which should be removed?
A. Off -- I would want to look just to make sure.
Q. Okay.
A. But I'm -- if I am -- I'd want to look just to make sure, but I know there are some that should not be there.
Q. All right. But looking at Merritt, there are a couple of places where Merritt is cited in your report. One is Page 17 in that paragraph we just looked at. Another is Page 28 in Section -- the "Pooled study regarding talc use and ovarian cancer" section.
It says some -- let's see, you're talking about the advantages of pooled studies, and you cited Merritt 2008.
A. Okay.

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Q. And then on Page 35, Merritt is cited. "Studies evaluating duration and frequency of perineal use, most have found an increased risk of ovarian cancer with increased exposure."

We already went through this paragraph earlier --

A. Yeah. Yeah.

Q. -- and discussed Merritt a little bit in that context.

MR. ROTMAN: Page 30 -- the last one was Page 35?

MS. AHERN: Thirty-five. Yeah. I apologize. We may not have discussed Merritt.

BY MS. AHERN:

Q. But looking at Merritt now, you're aware that Merritt looked specifically at inflammatory conditions as part of their exploration of the hypothesis that chronic inflammation could lead to ovarian cancer; is that right?

A. Yes. There was a component from what I remember.

Q. They say in the abstract that "Chronic inflammation has been proposed as the possible causal mechanism that explains the observed

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association between certain risk factors such as the use of talcum powder or talc in the pelvic region and epithelial ovarian cancer."

Do you see that? It's in the abstract, the first sentence?

A. Yeah. Okay. The first sentence.

Q. Okay. They go on to say, "To address the issue, we evaluated the potential role of chronic local ovarian inflammation in the development of the major subtypes of epithelial ovarian cancer."

Do you see that?

A. Yes.

Q. Okay. And just want to ask you: They conducted the study as a case-control study looking at 2319 women with epithelial ovarian cancer; correct?

A. I don't remember the exact number, but I will -- I will --

Q. I think that's -- that's okay.

A. I don't remember the exact number.

Q. Okay. So they looked at a number of factors that are theoretically associated with chronic inflammation, didn't they, including pelvic inflammatory disease and talc use,

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endometriosis.

And do you see if you turn to -- I'm trying to get through this quickly. You're welcome to point out anything you want, but I kind of want to move us along.

A. Okay.

Q. If you look at the "Discussion" section, I, unless I missed it, on Page 174, the right-hand column, second full paragraph, they note that "It has been hypothesized that talc is linked to ovarian cancer development through inflammation. However, evidence linking an inflammatory response with talc contamination of the ovaries is lacking."

Do you agree or disagree with that statement that evidence linking an inflammatory response with talc contamination of the ovaries is lacking?

A. I don't know if I would phrase it that way. Have there been studies that have followed talc from application up to the ovaries and documenting an inflammatory response after talc? No. There's not going to be that study.

That would be -- I don't think you could do that study today with talc being called by the

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IARC a possible carcinogen. I don't think you could design that study right now and do that in women.

But, again, I think -- I think it's still a highly compelling, plausible mechanism because we know talc can cause inflammation, and inflammation is associated with certain cancers, including certain types of ovarian cancers.

So I don't know if I would state it that way.

Q. When you say inflammation is associated with ovarian cancer, what studies are you referring to?

A. I'm referring to, for example, clear cell carcinomas that have arisen from endometriotic lesions that we've talked about before.

Q. And those cells are -- the originating cells are thought to come from the endometrium itself, the uterus; correct?

A. I don't know if we know for sure. I mean, is it endometriosis that's in the ovary causing chronic inflammation in the ovarian cells that are causing the clear cell? I don't know if that's been completely delineated.

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Q. But there are markers that will distinguish ovarian surface epithelial cells from endometrioid cells which resemble endometrial cells; correct?

A. There are some stains that you can do. But, again, I don't know if it's going to be -- been completely elucidated.

Q. Are you aware of recent studies that have demonstrated that there is some abnormality in the endometrium of women who develop endometriosis when compared to women who don't develop endometriosis?

A. I'm aware that retrograde migration of the endometrium is thought to -- has been associated with endometriosis. I don't know what you mean by "abnormalities" of the -- you have to be more specific. I can't --

Q. I don't have the publication with me. I was just asking if you were aware of those studies.

A. I probably read them at some point, but off the top of my head, I'm not really sure without knowing more specifically.

Q. And would you agree that the studies, though, that show a decreased risk of ovarian

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cancer for women who have tubal ligation are studies -- well, are more highly associated with endometrioid clear cell carcinomas than with high-grade serous?

A. With tubal ligation, off the top of my head, I believe that's -- that that's the case.

But with salpingectomy, which removes the fallopian tube fimbriae, there's -- that decreases the risk of serous carcinomas.

Q. To a lesser extent, then, the decrease for clear cell and endometrioid, which some people have suggested supports the retrograde migration of endometrial cells into the abdominal cavity?

A. Some people have said that that supports the retrograde migration of the endometrial cells. That is correct.

Q. And I got off topic. We're looking at Merritt. Page 174, if you look, let's see -- here it is. Sorry. I apologize, on Page 175.

The very bottom of the summary paragraph, it says, "The elevation in ovarian cancer risk associated with use of talc in the perineal region that we and others have observed has been regarded as the main evidence supporting an

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inflammatory mechanism in the development of epithelial ovarian cancer. However, experimental evidence that perineal talc use elicits an inflammatory response in the ovaries is lacking, and overall, we conclude that chronic inflammation does not play a major role in development of ovarian cancer."

Is there a reason you didn't cite the Merritt study in your report specifically when discussing evidence of chronic inflammation and ovarian cancer, a link between those two?

A. In the places that I -- let me just double-check. Places that I mention, was I not -- I wasn't talking about inflammation. Is that what you're --

Q. Yes. You agree you cited Merritt in several places in your report?

A. Yes.

Q. But you didn't cite anything about the inflammation findings from Merritt.

A. I'm not sure I can completely agree with their conclusion. It's true we don't have -- like I mentioned before, we don't have a study that has looked at women who use talc, follow it up, and then see chronic inflammation

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in the ovary.

But I think that's going to be -- again, we don't know how long that chronic inflammation is going to be there. We don't know what dose is getting into the ovary.

I still think -- and, again, this is the plausibility part of it -- I think there's still compelling evidence that talc can cause an inflammatory response that would explain the risk of increased risk of ovarian cancer with talcum powder products.

So, I mean, I certainly read this. It had some good information in it. I don't think I was purposely trying to leave out something that had evidence. This was their opinion.

And I'm -- I don't know if I would phrase it that way, the exact words that they use.

Q. Well, if those are exactly their findings here -- if you look at the top of the summary paragraph, "In summary, most factors that could potentially cause ovarian inflammation such as pelvic inflammatory disease, HPV infection, and postpubertal mumps were not associated with a significant elevation in ovarian cancer risk in our study. In addition, the expected corollary,

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an inverse association with regular use of anti-inflammatory medications, was also not observed -- or was not observed."

A. Yes. Yeah. Yeah.

Q. They looked at multiple sources or multiple causes of inflammation in the pelvic region and did not find an association with the risk of ovarian cancer, and they didn't find a decreased risk in people that used inflammatory -- anti-inflammatory medications.

A. I think I mentioned --

Q. So this is an inflammation study, isn't it?

A. Yeah. I think I mentioned in -- about NSAIDs that I might have cited them in that section, that the evidence was not consistent with NSAIDs, if I remember correctly.

I definitely looked at this paper when I was looking at NSAID and aspirin use and certainly inflammation as well. So...

Q. It's actually not cited anywhere with NSAID use or regarding inflammation at all.

So maybe it was an earlier draft and was removed at some point?

A. It's possible.

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Q. And you also -- you cite -- you do cite some of the NSAID studies and aspirin studies, but you leave out others. You leave out Baandrup 2013, which was a negative study; Bonovas, 2005, which was a negative study; Ni, 2012, which was a negative study.

When you did your review of inflammation including anti-inflammatory medications and the risk of ovarian cancer, did you pull out more studies in review than you actually included in your report?

A. Yes. There are definitely more studies than were cited in my report.

Q. Is there a reason you didn't cite the negative studies?

A. I didn't intentionally leave out the negative studies, but I do mention that the evidence had been inconsistent with NSAID.

Q. Okay. And you mentioned the Heller study in a couple of places. You mentioned several times that part of your plausibility opinions involve the fact that talc has been observed in the ovaries; correct?

A. Can you show me? I'm sorry. I just want to make sure.

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Q. I'm sorry. I'm just referring generally.

Do your opinions, in part, depend on the finding of talc in ovaries?

A. No. Because I think, again, it's difficult to find talc in the ovaries. So I would not expect to see -- to find, to histologically find talc in every ovary of a woman who has used talcum powder products. I think that would be extremely difficult to do in every patient.

And I know we talked about the MUC-1 theory earlier, but if that is the mechanism, that would not require talc to get to the ovary.

So, no, I don't think it's necessary to find talc in the ovary in every woman to come -- that's a user.

Q. Let's talk about evidence for talc-induced inflammation in the ovary.

For instance, you've cited the Heller study from 1996 in your "Migration translocation, inhalation, and lymphatic transport" section on Page 14.

A. Mm-hmm.

Q. Heller actually states in their study

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that they did not find on their H&E slides any response -- any expected response to talc particles.

Do you remember that?

A. I do remember that vaguely. Yes.

Q. Did any of the studies that you cite in that section for the proposition that talc has been found in ovarian tissue, did any of those find a reaction to talc in the ovaries?

A. I don't believe the studies that have found talc in the ovaries have all looked for chronic inflammation. Some of them, if I'm remembering correctly, I don't know if they all looked histologically; but the ones that did, I don't believe they had mentioned finding chronic inflammation near the talc particles.

But again, you know, depending on how long that inflammatory response is going to be there, depending how long that particular talc particle has been there, you wouldn't necessarily expect to still see it 20 years later.

Q. Okay. In the Heller study, they looked at ovarian tissue -- ovaries from one of their subjects who had 1.7 or approximately 1.669 million particles per gram of wet weight by

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electron microscopy and found on hematoxylin and eosin stain slides from the analyzed sections of the tissue that no evidence of response to talc such as foreign body giant cell reactions or fibrosis in the tissue.

Is that consistent with the other studies that have reported findings from H&E have also reported no response to talc or supposed talc they found?

What is an alternative explanation for how microscopists doing these sorts of studies might find talc by TEM or SEM without any histologic response --

MR. ROTMAN: Objection.

Q. -- to talc in the tissue?

A. Well, I think I addressed that a little earlier. Again, I don't know -- we don't know how long a chronic inflammatory response would be there after a particular talc particle lands on the ovary.

But the important thing would be that that chronic inflammation, the initial chronic inflammation, whenever that may be, however long it is there, causes oxidative stress that induces an oncogenic change in an ovarian cell or

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fallopian tube cell, for that matter.

So -- and these are very small studies that looked at histologic -- that looked histologically for talc in these ovaries.

So, you know, I don't necessarily think -- I don't think that you would have to find chronic inflammation if you're looking at an ovary at a particular point in time when we're talking about long-term talc use from, you know, up to 20 years ago or something.

Q. Well, if they're finding 1.7 million particles per gram of wet tissue right then and there, and their slides from that time period don't show any response whatsoever to talc that they would expect to see, what's an alternative explanation?

A. An alternative explanation is that there was chronic inflammation, and it has since resolved.

Q. How about there might be contamination of their samples with talc, which is ubiquitous in many laboratories?

A. I believe they -- I have to look at the study to -- do you have the study?

MR. ROTMAN: Thank you. What number?

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MS. AHERN: What number are we on?

COURT REPORTER: Twenty-five.

MS. AHERN: Twenty-five.

MR. TISI: So 24 was --

MS. AHERN: We'll wait.

(Article entitled "The relationship between perineal cosmetic talc usage and ovarian talc particle burden" marked Exhibit 25.)

A. I believe they went through standard electron microscopy methods, which controls for contamination.

BY MS. AHERN:

Q. How?

A. I don't know if it goes through the whole -- but they're very careful in how they handle tissue before they prep for electron microscopy.

Q. Doctor, do you know where they got the tissue from?

A. Yeah. It's listed.

Q. Did they collect the tissue themselves from the patient in a particulate-free environment and handle it with particulate-free gloves in containers, or did they get it from

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hospital paraffin-embedded tissue?

If you look on Page 1508, "Ovarian tissue in blocks was reparafinized, rehydrated, blotted dry and weighed, and then digested with reagents."

A. So I think these women were talc users. I'm trying to find controls that they had ovaries from -- if I remember correctly, they had ovaries from fetal cases that did not show talc, if I remember correctly. I'm trying to find that.

Yeah. "In addition, the ovaries of two stillborn fetuses were analyzed as negative controls."

Q. Does it say anything about where those stillborn fetus ovaries came from and if they were handled in the same hospital in the same way that the parafinized blocks were handled?

A. If they didn't have a separate section of their methods how they handled it, it would be the same methodology.

Q. Well, assuming it's not contamination and there's still no reaction to talc, another alternative explanation might be that talc doesn't cause chronic inflammation in the ovaries.

A. But they didn't find talc in their

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negative controls, which were fetal females that would never have been exposed to talc.
Q. Except for after the tissues were taken from the fetuses and processed?
A. I'm just trying to find where they -- what they did.
Q. What I wonder and what I don't think is in the paper, unless you can find it, is an explanation for how the fetal ovaries were obtained and processed.
Did they come from the same hospital system --
A. It would be the same.
Q. -- from the laboratory so that any contamination that occurred to those tissues prior to the Heller group getting them was accounted for?
Or did they purchase them separately through a company or something else that handled them differently from the hospital samples?
MR. ROTMAN: Objection.
A. If those were obtained differently, it should have been in the methodology. So the fact that it's not there, the next sentence after they say, "In addition, the ovaries of two stillborn

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fetuses were analyzed as negative controls," that is where, if it had been a different methodology or different purchased ovarian cell blocks from fetuses, which I have never -- anyway, it would be -- it would be there. And it's not.
Q. Hmm. So my next question is: I had asked you earlier if there was an alternative explanation for why there's no tissue response seen in this study to talc particles, and you said it could be because the chronic inflammation was there and not there at the time that they looked at the H&Es?
A. Yeah. I mean, you're looking at an ovary at a very -- at one time point. So we don't know how long those talc particles were there. We don't know if -- how long -- we don't know how long the chronic inflammation is there.
But the important thing is that the chronic inflammation would cause an event to change to an oncogenic phenotype, gene type.
Q. So chronic inflammation is, by definition, chronic; correct? Doesn't just -- it doesn't just resolve in a couple of days.
It's ongoing; is that correct?
A. It is -- acute inflammation would be

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something that would happen over days. Chronic inflammation is generally longer, but it still resolves.
Q. And are -- for instance, pelvic inflammatory disease is -- the effects of pelvic inflammatory disease can be seen by pathologists for a very long time; correct?
A. You can see fibrosis. So...
Q. And one of the things that you mentioned earlier is that talc can cause fibrosis?
A. Talc can cause fibrosis. You get -- in the ovary, however, you will get surface fibrosis, generally, from the mesothelial cells in the surface.
But, again, you're not always going to have fibrosis with chronic inflammation, either.
Q. If it's chronic inflammation that is significant enough to lead to a transformative event, shouldn't you expect to see some evidence of that chronic inflammation?
A. Well, we don't know how much chronic inflammation is necessary to cause a carcinogenic effect.
Q. By analogy, wouldn't you look at

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something like ulcerative colitis and colon cancer since that seems to be a fairly well-established association?
A. Yes. And as soon as patients are diagnosed with ulcerative colitis and Crohn's disease, they are carefully followed at the beginning. We don't wait 20 years to start following them. We know that, you know, the risk is there. As soon as they're diagnosed, we know there is a risk for increased cancer, so we start surveying them.
Q. But there's massive evidence of inflammation -- tissue-damaging inflammation in ulcerative colitis; correct?
A. Not always massive, but there's chronic inflammation.
Q. Throughout the entire GI tract or bowel?
A. In -- it's not always the whole, but yeah, there's chronic inflammation in the intestines.
Q. There's nothing in the literature that suggests that talc causes that kind of an inflammatory reaction, is there?
A. That talc causes a chronic

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inflammation?
Q. That talc causes that sort of chronic inflammatory reaction.
A. Well, I showed you some excerpts where they mention lymphocytic and plasmacytic inflammation due to talc. We know that talc causes an acute inflammation. I know we weren't talking about acute inflammation, but we know it causes acute inflammation in the -- after a pleurodesis. And I'm sure you could have lymphocytes in plasma cells there too.
Again, I don't think it's the -- sure. The amount and duration of chronic inflammation, I mean, would that increase the risk? But even a small amount of chronic inflammation for a relatively short period of time, I think it's plausible.
And, again, this is all under the plausible thing that this would cause a mutagenic effect.
Q. Can you name other chronic inflammatory conditions that are not associated with cancer?
A. Chronic inflammatory conditions that are not associated with cancer? Well, I'm not sure we absolutely know every -- that a chronic inflammatory condition won't cause a cancer,

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but -- so I'm not really sure. I'm not really sure what you're getting at.
Q. Can you list five chronic inflammatory conditions?
A. That don't cause --
Q. Just list five chronic inflammatory conditions.
A. Well, we have rheumatoid arthritis that increases risk of lymphomas. We have Helicobacter pylori infections that increase gastric cancer. We have the ulcerative colitis, Crohn's disease, that increase the risk of cancer. Agent exposures like asbestos that causes chronic inflammation and causes cancer. HPV infection causes cancer. I mean...
Q. Can you name one that doesn't involve a virus or an underlying immune dysfunction?
A. I named asbestos.
Q. Asbestos.
And was there another?
A. Again, I don't know if we have all the data on potential carcinogens and whether or not they cause chronic inflammation for sure. I think that, you know, we're still getting that data.

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Q. Have you ever diagnosed a patient with a talc-related ovarian cancer?
A. It's entirely possible that I have, but I have not used polarized light microscopy on ovarian tumors, so it's possible I have and didn't look for talc -- didn't look for talc.
MR. KLATT: Objection. Nonresponsive.
Q. My question was: Have you ever diagnosed a patient with a talc-related ovarian cancer, meaning you have said, "Your cancer is related to talc use"?
A. Well, first of all, I wouldn't have said that if I'm not looking for talc.
But secondly, in our pathology reports, even though we're thinking and looking at causation, we're not necessarily putting in our individual patient reports what caused their cancer.
We're certainly putting the diagnosis together with their medical history and their -- to kind of make all the pieces fit together, but we're not necessarily in every patient putting out a report on what causes their cancer.
MR. KLATT: Objection. Nonresponsive.
MS. AHERN: Objection. Nonresponsive.
Q. I just want to know if you've ever

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actually diagnosed a patient with a talc-related ovarian cancer. It sounds like the answer is no.
If it is, it's okay. I need an answer.
A. I'm trying to answer your question. Honestly, it's entirely possible that I have.
But have I specifically put in a patient's report, "This ovarian cancer was caused by talc," no.
Q. Thank you. That's all I was asking.
What about at tumor boards? Do you attend tumor boards?
A. I do.
Q. Have you ever suggested in a tumor board meeting with other colleagues that a particular patient's ovarian cancer was caused by talc use?
A. I've certainly discussed with oncologists and radiation oncologists about my recent work. Again, it's been only in the last year and a half that I have really done this deep dive in this literature.
And I've certainly talked to radiation oncologists, oncologists about it at tumor boards in a way of sort of educating them about my findings, but we haven't discussed in the context

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of a particular patient.
Q. And were these discussions with radiation oncologists, were these people that focused on -- if they focus on -- gynecologic malignancies? Were they more pulmonary? Is there a difference with radiologists in terms of specialty?
A. There are some subspecialties. In this one, they were more general radiation oncologists.
Q. Okay.
MS. AHERN: How much time do we have?
THE VIDEOGRAPHER: Fifteen minutes.
MS. AHERN: I'm going to turn it over to my colleagues so they have an opportunity to ask questions. Thank you very much. I appreciate it.
THE WITNESS: Thank you.
MR. KLATT: How much time do we have? We're at 6:37 right now.
Are you ready for me to continue?
CROSS-EXAMINATION
BY MR. KLATT:
Q. Dr. Kane, are you ready to continue?
A. Yes.

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Q. Can you hear me okay?
A. Yes.
Q. Yes. Dr. Kane, my name is Mike Klatt, and I represent a company called Imerys Talc America in this case.
Before this lawsuit, have you ever heard of Imerys Talc America?
A. I don't believe I had, no.
Q. Do you know what Imerys Talc America does?
A. From my understanding, they mine talc, and they supply -- they're the talc -- one of the talc suppliers for Johnson & Johnson.
Q. You said earlier you reviewed an exhibit of Julie Pier's deposition.
Do you know who Julie Pier is?
A. I know she was a designated representative. I don't know if it was for J&J or for Imerys off the top of my head.
Q. Ms. Pier works at Imerys, and she's an expert microscopist and at analyzing talc for any extraneous substances like asbestos.
She testified that the evidence you looked at did not indicate in any way that talc that ended up in Johnson & Johnson's baby powder had

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asbestos in it.
Are you choosing to believe the plaintiffs' asbestos experts over Ms. Pier's testimony?
MR. TISI: Objection.
A. Again, I think these were pieces of information for me. I wasn't relying on her -- the exhibit from her testimony for my general causation. I wasn't -- and I didn't see Dr. Longo's reports until very late in my process from what I recall.
It's interesting information for me. It's informative in that if the talcum powder products cause [sic] asbestos, that certainly lends significance to plausibility. But I'm --
MR. ROTMAN: Do you want to reread your answer there? I think you misspoke.
THE WITNESS: Okay. Sorry.
A. Yes. I did. If the talcum powder contains asbestos, that certainly adds to the plausibility. But I'm not opining on whether or not talcum powder products contain asbestos.
Q. And you wouldn't have the expertise to decide that Dr. Longo's testimony about asbestos in talc is more credible than Ms. Pier's testimony about asbestos in talc, do you?

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A. I have a, I would say, cursory knowledge of how they would test for asbestos. I couldn't say that I am an expert in the methods that they use to detect asbestos.
Q. But my specific question is: You don't have the expertise to determine that Dr. Longo's testimony about asbestos and talc is more credible with or more believable or more scientifically valid or less scientifically valid than Ms. Pier's testimony about asbestos and talc; correct?
That's my question.
A. Again, it's pieces of information for me. I don't know anything, really, about Dr. Longo versus Ms. Pier. I just have seen the exhibit from Ms. Pier's testimony and Dr. Longo's report, but I don't have more information nor have I really sought it out about their credentials. I was just using it as pieces of information.
Q. But again my question is: You have no ability or expertise on your own to judge whether Ms. Pier's testimony that there's not asbestos in talc is correct or Dr. Longo's testimony is correct. That's not an area of your expertise;

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correct?
A. It -- I wouldn't say I'm an expert in that area.
Q. You mentioned earlier in response to Ms. Ahern's questions, you talked about heavy metals.
Are you aware that IARC has not singled out a single heavy metal as a cause of ovarian cancer?
A. Yes. I have seen that. I have reviewed the IARC monograph on heavy metals, and I'm aware.
But, again, it's another sort of piece of the plausibility puzzle. If we -- we know that some of them are either listed as carcinogens or probable carcinogens. If they're in the talcum powder product, that's just another piece of the biological plausibility puzzle. And I --
Q. Well, is it your -- I'm sorry. I didn't mean to cut you off.
A. No. Sorry.
Q. Is it your testimony that if something is considered a carcinogen for one organ system by IARC, that it's capable of causing cancer in all organ systems?

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A. As I've testified several times here today, I think different tissues respond in different ways to different carcinogens. So I would not make a blanket statement that a carcinogen in one site will definitely cause cancer in another site.
However, having carcinogens, known carcinogens in a product, it can add to the biological plausibility. And we're not talking about these heavy metals sort of in the environment. I mean, these are -- there's evidence that they are in a product that's used regularly and frequently.
Q. Are you -- are you aware that the same, exact heavy metals are in bottled drinking water?
A. So, again, I don't know what the levels of these heavy metals are in drinking water. I know that they are found in the environment commonly.
Q. Are you aware they're in foods?
A. I'm aware that they are in the environment and foods regularly. Yes. But --
Q. Are you aware they're in multivitamins?
MR. ROTMAN: Wait. Wait.
I was hearing a "but" and not a period

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at the end of the answer before you started your next question.
A. So I'm aware that they're in these things. What I'm looking at is a product that's used frequently and for -- in a lot of women for a long duration of time. So their exposure -- if they are in the talcum powder, their exposure to those heavy metals would be greater than the exposure they're getting in the environment.
Q. Those same, exact heavy metals are in drinking water, bottled water, food, and multivitamins that people take every single day, and there's no evidence that they cause ovarian cancer; correct?
A. There has not been a link with heavy metals to ovarian cancer specifically as of yet.
Q. And there's no evidence you're aware of that the tissue levels of any heavy metals are higher in talc users than in women who never used talc; correct?
A. I don't -- I'm not aware of that study being done.
Are you talking tissue levels?
Q. Blood levels --
A. Blood levels.

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Q. -- tissue levels. Anything you want.
You're -- there's no medical or scientific evidence that you would tell this court that the levels of heavy metals in women who use talcum powder in the genital area are higher than women who have never used talcum powder?
A. I'm not aware of studies that have been done that have looked at the levels of those heavy metals in ovarian tissue or blood levels.
Q. Earlier you mentioned there was a study about changing gene expression in the presence of talc in mesothelial cells?
A. Yes.
Q. The mere fact that you have changing gene expression in no way implies something is carcinogenic; correct?
A. It -- it's evidence that it's changing gene expression within those cells, and --
Q. If -- I'm sorry. Go ahead.
A. And the genes in that study that had increased expression are involved in the inflammatory -- are pieces in the inflammatory response.
Q. You're aware that many of those genes in that study were antioxidant genes and

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anti-inflammatory genes that were elevated; correct?
A. They can regulate or deregulate, and I think it's interesting -- let's say that they were antioxidant -- they were producing antioxidant enzymes. I think that is evidence that it's trying -- that the cell is trying to respond and is trying to prepare itself for an insult, an inflammatory insult. Otherwise, why would that gene be expressed?
So, I mean, there's increased and decreased regulation.
Q. But, Dr. Kane, you're aware that strenuous exercise can increase gene expression of prooxidants, antioxidants, proinflammatory, anti-inflammatory proteins; correct?
A. Strenuous exercise can increase antioxidants in proinflammatory, anti-inflammatory proteins.
But, again, I'm opining about a product that someone is going to be using regularly with frequency over a long period of time.
Q. You're aware that --
A. It just adds to the -- I'm not -- you know, I don't have an opinion about whether or

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not those heavy metals are in talc. I've looked at some evidence that they are there, but I don't have an opinion that they're actually in talc. It's just another piece of evidence, again, for the biological plausibility.
Q. Well, you're not saying that people who regularly engage in chronic exercise, chronic strenuous exercise, for a long period of time are at increased risk of cancer because they have increased gene expression, are you?
A. Well, there hasn't been epidemiologic evidence that is consistent that people who do routine strenuous exercise get cancer.
Q. The Buz'Zard study you cited, that actually showed that talc -- increasing doses of talc decreased release of reactive oxygen species from ovarian cells, not increased it; correct?
A. I believe it was different -- I would have to look at the study, but it was over different time periods. It fluctuated.
Q. The highest level of reactive oxygen species in the Buz'Zard study was the group of cells that had no talc applied at all; correct?
A. I'd have to re-review the study.
Q. Let's --

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MR. KLATT: Can we mark that?
MR. ROTMAN: Can we get a time check?
THE VIDEOGRAPHER: 6:30.
MR. ROTMAN: Thank you.
(Article entitled "Pycnogenol reduces Talc-induced Neoplastic Transformation in Human Ovarian Cell Cultures" marked Exhibit 26.)
MS. AHERN: That's 26.
Q. Referring to Exhibit 26, Dr. Kane, is this the Buz'Zard study you were mentioning earlier?
A. Yes, this is it.
Q. And if you'll flip over to Page 3 -- excuse me, 582, Figure 3, do you see Figure 3 is --
MR. ROTMAN: Can I have a copy of that, please?
MR. KLATT: I'm sorry?
MR. ROTMAN: I'm waiting for a copy of that.
MR. KLATT: Oh. Yes. We do provide copies.
MR. ROTMAN: This is Exhibit No. 1?
THE WITNESS: I'm sorry. Which table?

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MS. AHERN: Twenty-six.
BY MR. KLATT:
Q. Figure 3. Page 582.
MR. ROTMAN: What exhibit are we on?
COURT REPORTER: Twenty-six.
MR. ROTMAN: Thank you.
BY MR. KLATT:
Q. And you see Figure 3 is "ROS." That stands for reactive oxygen species?
A. That's --
Q. And, by the way, ROS are generated by every cell of the body every day, 24 hours a day; correct?
A. Reactive -- you do see it in daily cell life. But, again, I'm talking about an additional exposure, an agent that that is being applied in addition to what you're seeing on -- basically the cell has, as we just discussed, they have ways of mitigating reactive oxygen species.
The cell can increase their antioxidant enzymes, but at some point, they can get overloaded. So if you're giving it a higher dose at a higher frequency than those systems can handle, you're going to have an increased risk of

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mutagenesis.
Q. Well, let's look at what Buz'Zard found when talc was applied to surface ovarian cells.
Do you see that? That's Figure 3A up at the top?
A. A, up at the top. Yes.
Q. And you'll agree with me, you see on the Y axis it says "Percentage of reactive oxygen species generation in OSE2a cells"; correct?
A. Yes.
Q. That's ovarian surface epithelial cells; correct?
A. Yes.
Q. And you'll see at the zero talc level on the X axis --
A. Mm-hmm.
Q. -- that had 100 percent talc -- excuse me -- a 100 percent reactive oxygen species generation at all three time periods; correct?
A. That is correct. And --
Q. And when talc was applied?
MR. ROTMAN: Wait. Wait.
Did you finish your answer?
A. Well, we were just talking about how cells can have innate ROS generation.

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Q. And this graph shows that as you applied increasing doses of talc, the level of generation of reactive oxygen species in the ovarian cells went down.
It didn't go up; correct?
A. Well, it goes up at -- what's the 50 -- the 50 micrograms per milliliter. It goes up at that dose at the 120 hour, and then it goes up at the 200 microgram level.
Q. That's not talc, is it?
A. I'm sorry. I'm looking at -- I'm looking at -- it says "Talc micrograms per milliliter," and then it lists the different hours on the right; that they're color-coded to the different hours.
Q. And 17 out of the 18 measurements they took when talc is applied to ovarian cells showed the ovarian cells generated less reactive oxygen species than no talc at all; correct?
A. And I --
Q. Is that correct?
A. It looks like at different periods of time at the 100 micrograms and 500, there was less than the lower. But I'm not sure what the threshold dose would be for optimal ROS

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generation for each talc microgram.
Q. Do you see in the far right column, they applied 200 micrograms of hydrogen peroxide?
A. Yes.
Q. And that resulted in a 200 percent increase in reactive oxygen species during those time periods; correct?
A. That is what it says. Yes.
Q. And that's their positive control; correct?
A. Let me just double-check.
If I'm remembering the study correctly, yes, you are -- you are right.
Q. People gargle with hydrogen peroxide; correct?
A. They shouldn't.
Q. Well, you know, it's allowed on the bottle.
You know that; correct?
A. If you're telling me they gargle with it, that's fine.
Q. Well, they put it on cuts; right?
A. They shouldn't put it on cuts. It's actually --
Q. It's sold for that, isn't it?

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A. I think most MDs would tell you that it's probably better not to use hydrogen peroxide on open cuts because it can cause a pretty severe reaction.
Q. You're aware that it's sold over the counter in stores every day for -- as an antiseptic?
A. Talcum powder is sold for everyday use on babies.
Q. So are you telling us that hydrogen peroxide now causes cancer?
A. I'm saying that it will release ROS species generation.
Q. Far more than talc; correct?
A. Based on this study, it appears that way.
Q. And you --
A. This one study.
Q. You agree with me this shows, as you apply talc, reactive oxygen species in ovarian cells decreases.
It doesn't increase at 17 out of 18 time points; correct?
A. They're -- I will agree with you, except there is a time point where it is

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increased. And I don't know -- my caveat is I don't know where the threshold would be where the ROS would stop being generated.

Q. Is aspirin approved by any pharmaceutical company or recommended by any medical organization for prevention of ovarian cancer?

A. That is not on the label description.

Q. If aspirin prevented ovarian cancer, don't you think it would be marketed for that purpose?

MR. TISI: Objection.

MR. ROTMAN: Objection.

A. I'm sure it may be after years of FDA red tape and approval, but the literature -- again, I've said the literature is not as beefy as the epi data when we're looking at aspirin and NSAIDs.

NSAID, in particular, is not as consistent. The aspirin data does appear to be consistent in lowering the risk, but there are not a lot of studies looking at this yet.

Again, though, just a piece of the puzzle for a biologic plausibility.

Q. Well, certainly, we're not at the point

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for aspirin and ovarian cancer that we are, for example, with aspirin in terms of cardiovascular risk; correct?

A. I would agree with that sentiment.

Q. And doctors and medical organizations have recommended aspirin for reduction of cardiovascular risk; correct?

A. That's correct. Although the dosage has -- as of late, they're kind of parsing out the -- they're reevaluating what dosages, but you're correct.

Q. And you can't cite a single medical organization that at this point in time says the evidence that aspirin reduces ovarian cancer is sufficient that women should take it on a regular basis to reduce ovarian cancer; correct?

A. Well, I think I've said there aren't that many studies yet. It's only -- that I'm aware of, there are only a handful. They've been consistent with aspirin. Not so much with NSAID. That's, I think, as far as the evidence takes us as this point.

Q. There's actually studies showing that chronic aspirin ingestion doesn't decrease ovarian cancer risk; correct?

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A. I have to look at the studies. There might be one where it wasn't statistically significant, but I think the majority of the ones that looked at aspirin use showed a decreased risk of ovarian cancer.

Q. Are you -- are you a member of the International Society of Gynecologic Pathologists?

A. I don't think I'm a member currently. No.

Q. Have you ever been?

A. I believe so.

Q. It's not on your CV.

A. Okay. I'm not currently. I know that.

Q. Are you a member of the American Society of Clinical Pathology?

A. I actually am.

Q. It's not on your CV.

A. Okay. That should be updated, then.

Q. Have you ever been a member of any working group or organization on the classification of female reproductive organ tumors?

A. No. I can't -- no.

Q. You mentioned the Surgeon General's

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report in 1964. You're aware that when that came out about smoking, there were numerous studies in the literature at that point in time showing that the chemicals in cigarette smoke actually damaged DNA and resulted in cancer; it wasn't based just on epidemiology?

A. I think epidemiology -- my point was that the epidemiology was the sort of first -- there were pathologists that had noticed on autopsies in patients that smoked -- it was actually pathologists and a surgeon in the early years -- that had noticed some changes, some squamous metaplastic changes.

But it was really the epi data that sort of drove the research on smoking and tobacco initially. But, again, there were some studies that had shown some pathologic changes in smokers. That's true.

Q. You're aware that the cohort studies, the hospital-based case-control studies, and the population-based case-control studies all uniformly showed that smoking increased the risk of lung cancer; correct?

A. That's correct.

Q. And that's not true for talc and

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ovarian cancer; correct?
A. Well, I have some issues with the cohort studies.
Q. I know that.
But my statement is true; correct?
A. But I think it's relevant because the cohort studies, I don't believe, followed patients for a long enough time.
The Nurses' Health Study only asked about talcum powder use once in 1982, so there's certainly room for misclassifications of users as never users.
And some of -- some of -- again, there's smaller numbers because it's a -- it's a cohort study.
Q. You're aware that the National Cancer Institute doesn't agree with you on that, aren't you?
A. I have seen the NCI website. I certainly considered what they say about it. I don't know if they have done the same type of analysis as I've done. I don't believe it's on their website what methodology they used and what literature they reviewed.
So I'm aware of what they've stated. But,

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you know, I've still done this extensive review that I'm not sure they did to come to my conclusion.
Q. You honestly don't know what the NCI did in terms of review to come to their conclusion, do you?
A. They didn't state what they did, so I do not know. So that would -- but that's something that I'm thinking about when I'm taking into consideration.
Q. And you are aware that they just updated their statement that the evidence does not support a link between talc and ovarian cancer in January 2019, the same month we're sitting here today?
A. I don't know if I've gone to the NCI website this month.
But I'm also aware of Health Canada that came out and did -- and we know what the methodology and literature they -- they spelled it out very clearly what their methodology was, what literature review they did, and they came to the same conclusion that I did.
MR. ROTMAN: Off the record, Mike?
MR. KLATT: Let me just follow up on

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that one statement.
Go ahead.
MR. ROTMAN: If you want to do that, that's fine.
BY MR. KLATT:
Q. That draft -- Health Canada issued a draft assessment that's undergoing a 60-day public comment period; correct?
A. That's true.
Q. And then they have up to two years to decide whether to take any action or no action at all; correct?
A. Well, there's two pieces of that. From my understanding is that they've already done the scientific. They've already done the literature review. They've already done their Bradford Hill analysis, and they've come to the conclusion that they've come to.
And then there's the public commentary. And then there's the regulatory aspect of it.
Now, I am -- I would not claim to be an expert in regulatory. I know we have regulatory experts that are coming on. But in -- from my understanding, the regulatory aspect is different than the scientific aspect.

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MR. ROTMAN: Mike, you're done? I just want to --
MR. KLATT: I'm through.
MR. ROTMAN: I just want to go off the record.
We're done with seven hours.
MR. KLATT: Yes. I'm done.
MR. TISI: Let's take a minute.
THE VIDEOGRAPHER: Off the record, 6:31 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Back on the record, 6:40 p.m.
CROSS-EXAMINATION
BY MR. ROTMAN:
Q. Dr. Kane, I know it's been a long day for you, but I'm going to ask you a few questions. I will be brief.
A. Okay.
Q. At one point today, you were asked some questions by Attorney Ahern about certain negative studies on inflammation, and she mentioned Bonovast 2005 and Ni 2012, which she asked you about.
Do you recall that?

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A. Yes.
Q. She did not show you those studies, did she?
A. I don't believe I saw them.
Q. Are you able to agree with her characterization that these were negative studies without having -- without looking at them?
A. I should have asked for them and had them in front of me while asking questions.
Q. Now, you were asked questions --
A. I mean answering questions.
Q. -- throughout the day about inflammation as a biologically plausible mechanism for explaining talc causing ovarian cancer in light of the epi study findings.
A. Yes.
Q. You were also asked questions about cigarette smoking at various times throughout the day?
A. Yes.
Q. Does cigarette smoking have an inflammatory effect?
A. Yes.
Q. What is the --
A. It does cause chronic inflammation.

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Q. You were also asked questions about heavy metals being present in food and water and vitamins; correct?
A. I remember. Yeah.
Q. Do -- what is different between those circumstances and the situation that we have been discussing all day today involving talcum powder?
A. With talcum powder, we do have the epi data that are consistent and show an increased risk of ovarian cancer with talcum powder use.
Q. And with respect -- you were asked some questions in relation to the Buz'Zard study about hydrogen peroxide and the reactive oxygen species reaction?
A. Yes.
Q. Are you aware of any evidence that hydrogen peroxide -- the effect of hydrogen peroxide in the female genital tract?
A. I'm not aware that women routinely use hydrogen peroxide in the female genital tract.
Q. And is there anything in particular about the -- that part of the anatomy that where certain agents, exposure to certain agents, would raise any particular concerns -- strike that.
I think that was a bad question, so I'll just strike that.
You were asked questions about surgical gloves and surgical-grade talc on surgical gloves.
A. Yes.
Q. Do you recall that?
A. Yes.
Q. And I think you were asked if you were aware of any studies linking the use of talcum powder on surgical gloves with the occurrence of ovarian cancer.
Do you recall that?
A. Yes.
Q. Is there a difference, a notable difference, between talcum powder on surgical gloves and the talcum powder products in perineal use that, regardless of the constituent of the powder, that you would want to point out?
MR. KLATT: Objection. Form.
MS. AHERN: Same.
A. So a patient's exposure to surgical gloves are going to be infrequent and not of long duration. It's not the same type of exposure as regular and frequent application of perineal talcum powder that we're seeing in the epi data.

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MR. ROTMAN: No further questions.
It's 6: --
(Discussion off the record.)
MR. ROTMAN: You're right.
BY MR. ROTMAN:
Q. I have some questions for you about your testimony on the Harlow paper.
A. Okay.
Q. Can you pull that out in front of you, which was Exhibit 20?
A. Okay.
Q. Can you turn to Table 3.
A. Okay.
Q. And do you recall that you were asked questions about dose-response in this study?
A. Yes.
Q. And do you recall that you were specifically asked questions about this Table 3?
A. Yes.
Q. Could you look at the middle part of Table 3, at the column with "adjusted odds ratios"?
A. Yes.
Q. What can -- what do you observe with respect to the adjusted odds ratio as the -- as

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the -- as the number of applications goes from less than 1,000 to greater than 10,000?
A. The adjusted ORs go from -- the null, 1.0 at none, 1.4 at less than 1,000, to 1.7 at greater than 10,000.
Q. And so what, just looking at the adjusted odds ratio, what --
A. It's an increase with increased --
Q. -- what is your takeaway?
A. So it does show an increased odds ratio with increased applications.
The confidence intervals do include the null, but they're -- the higher end, it's higher confidence interval at the upper end.
And it's not very far from the null on the lower end.
And it, in fact, includes -- it's 1.0 at greater than 10,000.
Q. And so for the 1,000 to 10,000 applications, the lower bound of the confidence interval is .9?
A. Correct.
Q. And how close is that to being a statistically significant finding?
A. Very close.

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Q. And can you also take a look at the discussion on that page in the left-hand column in the paragraph that begins with "We also examined"?
A. Okay.
Q. Is there a discussion in that paragraph concerning the author's discussion of dose-response?
A. Yeah. There's a sentence that states, "The categorical analysis showed that relative to nonusers, the risk was greatest in women who applied talc at least once per day. When years of use was included as a continuous variable, the test for linear trend was 3.32, p-value of .07.
"The categorial analysis show that relative to nonusers, women who applied talc for more than ten years were at a 60 percent greater risk for ovarian cancer. Likewise, perineal applications of talc early in life, before age 20, or applications within six months of diagnosis reference age for controls produced the stronger ORs."
Q. And I'd like to also call your attention to the page 24 in the right-hand column.

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A. Yes.
Q. And this is -- this is in the "Discussion" section of the paper; is that right?
A. Yes.
Q. And do you see in the paragraph that I'm pointing to that begins with "Our study"?
A. Yes.
Q. Could you read into the record and comment on the last sentence in that paragraph.
A. "Daily versus less-than-daily talc use and talc use for more than ten years versus less than ten years were associated with greater risk for ovarian cancer."
Q. And can you comment on that?
A. So that does show a trend for a dose-response.
MR. ROTMAN: Okay. So I have 6:48. You've got eight minutes.
RECROSS-EXAMINATION
BY MR. KLATT:
Q. That Harlow study you were just looking at --
A. Yeah.
Q. -- is that the 1992 Harlow study?
A. It's the 1992 from Exhibit 20.

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Q. And can you look on the last page of this study, the page where the article ends and the reference begins.
Did Harlow find the strength of association between genital use of talc and ovarian cancer was strong or weak?
A. So they use -- they say, "Because the overall association between genital use of talc and ovarian cancer remains weak."
And, again, "weak" is sort of a relative. I've seen weak to moderate with this odds ratio. And this is also 1992.
MR. KLATT: Object. Nonresponsive.
Q. I'm simply asking you, Dr. Kane, does Harlow say strength of association between ovarian cancer and talc use is strong or weak?
A. Well, I'm putting it in context. He states -- I agree with you that's what the words say, but I'm putting it in context in that "weak to moderate" is used amongst epidemiologists for this level of overall risk.
And this is 1992, so there wasn't the subsequent studies that have gone on that show consistent, similar overall risk odds ratio.
Q. And would it be correct that the

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statement that I asked you to read says in full, "Because the overall association between genital use of talc and ovarian cancer remains weak, it is unlikely that this exposure disease pathway is the principal one involved in ovarian cancer etiology"?

Is that what Harlow said?

A. That's what it states. But, again, that is 1992. This is the very beginning of the epi data looking at this exposure and ovarian cancer.

MR. KLATT: Object and move to strike everything after "That's what it says."

Q. And, by the way, the odds ratio that Harlow found overall was 1.5.

And that's even a little higher than the odds ratios the more recent meta-analyses have shown; correct?

A. So --

Q. So they're even weaker than Harlow.

A. I'm sure some epidemiologists might take -- I'm not -- but, again, I've seen, even with 1.3 and 1.4, epidemiologists refer to that as "moderate."

So I don't know if it's semantics, but it's

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1.3. It's a 30 percent increased risk. In this case, 1.5, a 50 percent increase in risk. And in a rare disease like ovarian cancer, that's significant.

Q. And Harlow calls a 1.5 odds ratio weak; correct?

A. That's what he says in this 1992 paper.

Q. And you'd agree with me the more recent meta-analyses of talc and ovarian cancer have a lower odds ratio than 1.5?

A. They seem to be between 1.3 and 1.4, but the important thing to me is the consistency.

Q. And you're aware that epidemiologists say with case-control studies that odds ratios in the range of 1.0 to 1.5 are well within the range that can be explained by bias and confounding?

MR. ROTMAN: Objection.

A. I think all of the studies were aware -- all of the authors were aware of potential recall bias and confounding and sought to control as much as possible those factors in their control studies. Most of them, I feel, were relatively well-designed to assess for and adjust for multiple confounding factors.

And as far as recall bias, there's an

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element of recall bias in case-control studies, but the authors are aware. Many of them talk about that and discuss why they feel recall bias wasn't an explanation.

And, again, we're talking about multiple studies over numerous populations over different periods of time, most of them well before the general public knew about an association between talcum powder and ovarian cancer.

And even further, the fact that there's a strong association in the literature with serous invasive cancer would argue against a recall bias because the lay public is not knowledgeable about the histologic subtypes of epithelial ovarian carcinoma.

Q. Let me ask you this, Dr. Kane: We lawyers, before we have to go to trial, like to know if the prospective jurors have already made up their mind about the case.

Do you know if in any of these case-control studies where the women who had ovarian cancer, were they asked before they entered the study, "Do you have a preconceived notion about what caused your ovarian cancer?"

A. I'm not aware of a case-control design

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that would ask that question because even asking that question would potentially add an element of recall bias --

Q. But if a woman already --

MR. TISI: She wasn't finished.

Q. Were you finished?

A. I was going to say in a lot of these studies, they also asked about smoking history and other potential lifestyle issues in addition to talcum powder use that would -- and yet, those types of questions didn't show an elevated risk like talcum powder products.

Q. Well, wouldn't you want to know -- before you interviewed the women who have ovarian cancer, wouldn't you want to know if they have a preconceived notion about what caused their ovarian cancer so if you didn't exclude them from the study, at least you could take that preconceived bias into account when you did the statistics?

A. I would think if you're designing a case-control study and trying to avoid recall bias, there are better ways to do that because just by asking, "Do you have a preconceived notion about it?", you're introducing potential

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bias because they might think, Oh, maybe there is an association. And you're adding bias, potentially, that way.

Q. You mentioned cigarette smoking just a minute ago in response to Mr. Rotman's questions.

And you said cigarette smoking involves a chronic inflammatory condition in the body; correct?

A. There is an inflammatory response in the body.

Q. But cigarette smoking has not been shown to increase the risk of the two most common forms of ovarian cancer, which is serous invasive and endometrioid invasive; correct?

A. So, again, different tissues will respond to different agents in different ways. Mucinous carcinoma has been associated in some studies with smoking, so there is evidence that epithelial ovarian cancer can be caused by smoking.

MR. KLATT: Object. Nonresponsive.

Q. The two most common forms of invasive ovarian cancer -- serous, which is the most common, and endometrioid, which is the second most common -- have not been shown to be elevated

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as a result of smoking; correct?

A. The data has not shown an association between those two types with smoking.

Q. Even though smoking involves a chronic inflammatory state; correct?

A. But, again --

Q. That is -- did you hear my question?

Even though smoking involves a chronic inflammatory state; correct?

A. We're talking about different types of exposures.

Q. Does smoking --

A. Different agent --

MR. ROTMAN: One second, Mike.

Do you want an answer to the question? Because you're cutting --

BY MR. KLATT:

Q. My question is: Does smoking involve --

MR. ROTMAN: Wait. Wait, Mike. Let her answer the question, and then you're done because we're over.

Do you know what the question was?

A. Does smoking involve an inflammatory state?

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Yes. It involves an inflammatory state.

MR. KLATT: Thank you, Doctor.

MR. TISI: Just one question.

(Discussion off the record.)

MR. ROTMAN: We're done.

MR. TISI: Thank you.

THE VIDEOGRAPHER: Here ends today's deposition. Off the record, 6:58 p.m.

(Deposition concluded at 6:58 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

SARAH E. KANE, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

C E R T I F I C A T E

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

I, Janet M. Sambataro, a Registered Merit Reporter and a Notary Public within and for the Commonwealth of Massachusetts do hereby certify:

THAT SARAH E. KANE, M.D., the witness whose testimony is hereinbefore set forth, was duly sworn by me and that such testimony is a true and accurate record of my stenotype notes taken in the foregoing matter, to the best of my knowledge, skill and ability; that before completion of the deposition review of the transcript was requested.

I further certify that I am not related to any parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 28th day of January, 2019.

_____

JANET M. SAMBATARO

Notary Public

My Commission Expires:

July 16, 2021